

**Appeal No. 2016-1490**

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*In The*  
**United States Court of Appeals  
for the Federal Circuit**

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SHAUN L.W. SAMUELS,

*Plaintiff – Appellant,*

v.

TRIVASCULAR, INC., MICHAEL V. CHOBOTOV,  
ROBERT G. WHIRLEY, JOSEPH W. HUMPHREY,

*Defendants – Appellees.*

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*Appeal from the United States District Court for the Northern District of  
California in Case No. 3:13-cv-02261-EMC, Judge Edward M. Chen*

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**BRIEF OF THE APPELLANT SHAUN L. W. SAMUELS**

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March 10, 2016

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

Samuels v. TriVascular, Inc.  
No. 2016-1490

**CERTIFICATE OF INTEREST**

Counsel for the appellant, Shaun L.W. Samuels, certifies the following (use “None” if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Shaun L.W. Samuels

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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March 10, 2016

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## **STATEMENT OF RELATED CASES**

Shaun L. W. Samuels v. TriVascular, Inc. Corporation, Civ. Action No. 3:13-cv-02261 (N.D. Cal.) and the *inter partes* review of U.S. Patent No. 6,007,575 (“the ‘575 patent”) filed by TriVascular against Shaun L. W. Samuels. On February 5, this Court issued its ruling affirming the Board’s decision that all claims of the patent are valid. *TriVascular, Inc. v. Samuels*, 2016 U.S. App. LEXIS 1949 (Fed. Cir. Feb. 5, 2016). To the extent certain claim terms were construed or discussed, that decision may affect this Court’s decision in this matter.

## **JURISDICTIONAL STATEMENT**

The U.S. District Court for the Northern District of California had subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1338(a). On December 17, 2015, the district court entered a final judgment under Fed. R. Civ. P. 54(b) pursuant to the parties' stipulation of non-infringement, which followed the district court's claim constructions. On January 12, 2016, Samuels timely filed his notice of appeal in accordance with 28 U.S.C. § 2107(a) and Rule 4(a) of the Federal Rules of Appellate Procedure. This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1).

## **STATEMENT OF THE ISSUES**

The district court incorrectly construed the “means for injecting” and “means for inflating” terms. In its construction, the district court included “a valve” as part of the structure that performed the inflating/injecting function. Whether the district court erred by improperly including unnecessary structure in the means for inflation/injection terms.

The district court incorrectly construed the term “valve” as set forth in the patent. In its construction, the district court rejected plain meaning and used the narrowest embodiment from the specification. Whether the district court erred in its construction of the structural term “valve” by requiring it to perform in one isolated embodiment contrary to the inventor’s explicit use of the term broadly, and by requiring a sequence of method steps, rendered determination of infringement of the apparatus claim ambiguous.

The district court construed the term “inflatable and deflatable cuff,” “a cuff,” and “plurality of cuffs” in an inconsistent and narrow manner. The district court construed the term to require an inflatable chamber and that the cuff had to be “entirely” inflatable. Whether the district court erred in its construction of the terms “inflatable and deflatable cuff,” “a cuff,” and “a plurality of cuffs” to require an inflatable chamber, contrary to the specification and the doctrine of claim differentiation, and mandated further that it be “entirely” inflatable, thus negating the open ended nature of the patent claim.

## **INTRODUCTION**

This appeal concerns claim constructions that violate this Court's rules of claim interpretation. A construction should not import limitations restricting claims to particular embodiments or examples. But the district court construed the patent at issue to do just that, limiting the claims to specific embodiments and examples from the specification, even to the point of excluding a preferred embodiment. Further, the court improperly construed the claim in a way that renders it indefinite and virtually unenfranchiseable by a manufacturer of a device by requiring method steps in an apparatus claim. Finally, the court improperly believed the claim had to be construed to work in the narrowest method described in the specification, rather than interpreting the claims structure in their ordinary meaning and as taught specifically by the inventor himself. These errors require reversal and remand so that the case can proceed under a correct construction.

## **STATEMENT OF THE CASE**

### **I. The Parties**

Dr. Shaun L. W. Samuels is the owner and inventor of U.S. Patent No. 6,007,575 entitled "Inflatable Intraluminal Stent And Method For Affixing Same Within The Human Body" issued December 28, 1999 (hereinafter referred to as "the '575 patent"). APPX947, '575 patent, p. 1. TriVascular

Inc. and several individuals affiliated with TriVascular (collectively “TriVascular”) manufacture and sell stent grafts. APPX852-4, Second Amended Complaint, pp. 4-6. Samuels brought this action in May 2013 alleging that one of TriVascular’s products, the Ovation Prime Abdominal Stent Graft, in its various forms, was infringing the ‘575 patent. APPX63-8, Original Complaint. TriVascular is now owned by Endologix.

## **II. The Asserted Patent**

This litigation involves a single patent invented by a radiologist pertaining to an innovative stent apparatus used in, among other ways, the treatment of Abdominal Aortic Aneurysm, often referred to as AAA repair or Endovascular Aneurysm repair (EVAR). APPX877, Plaintiff’s Second Amended Complaint, p. 4. The invention also has many other potential uses as a stent and may be employed in many different situations. APPX61, ‘575 patent, Col. 6:32-46. U.S. Patent No. 6,007,575 is to an apparatus, the central feature of which is an inflatable cuff that has a circumferential ridge including an inflatable protrusion that upon inflation opens the tubular cuff and emulates a vessel. APPX59, ‘575 patent, Col. 2:28-38. In general the patented invention utilized an innovative cuff that has inflatable circumferential ridges that, upon inflation, help fix the cuff along the inner wall of a blood vessel. APPX48-62. ‘575 patent, Col. 2:28-38.

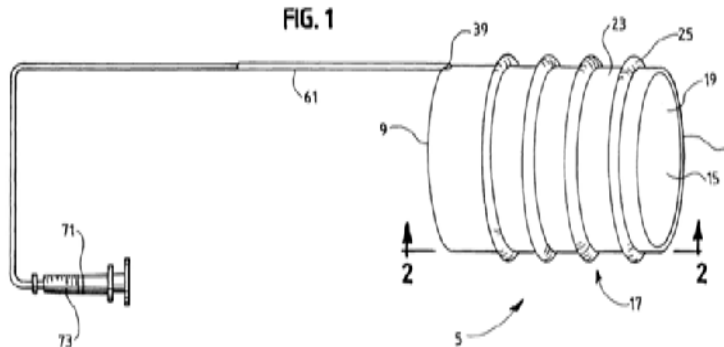
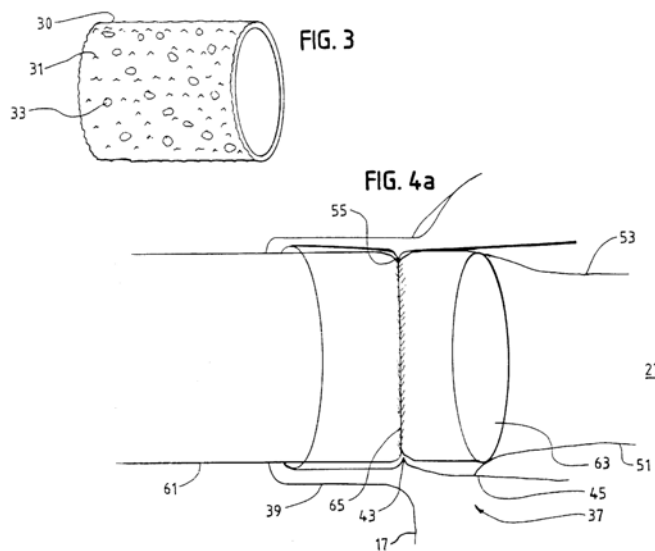


Figure 1, Samuels '575

More specifically, stent 5 includes one or more inflatable and deflatable cuffs 17. APPX60, '575 patent, Col. 3:24-32. Each cuff 17 is hollow and has a collapsible lumen 15. APPX60, '575 patent, Col. 3: 24-32. Cuff 17 also has an inner surface 19, an inlet 7, an outlet 9 and a friction-enhancing outer surface 23, as discussed in column 3, lines 25-32, and shown in Figure 1. APPX60, '575 patent, Col. 3:25-32. For friction-engaging purposes, outer surface 23 features inflatable protrusions in the form of at least one circumferential ridge 25 disposed about cuff 17, as seen in Figure 1 and described in column 3, lines 33-41. APPX60, '575 patent, Col. 3:33-41. When cuff 17 is in its fully inflated condition through inflatable ridges 25, which extend circumferentially, the ridges engage the interior of the tubular structure, without penetration, to affix cuff 17 along the tubular structure and prevent cuff 17 from moving in a longitudinal direction. APPX60, '575 patent, Col. 3:54-59. Stent 5 also includes a

means for injecting or inflating with an inflation material and one or more valves, such as valve 55 shown below, for permitting entry of the inflation material into cuff 17, thereafter preventing leakage. APPX60, '575 patent, Col. 4:8-23. Once the material hardens, the inflation tubing 61 is removed and the device remains in the body. APPX60, '575 patent, Col. 4:24-32.



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The patent survived a challenge in *inter partes* review, all claims of the patent were held valid, and the holding of validity was affirmed by this Court on appeal. *TriVascular, Inc. v. Samuels*, 2016 U.S. App. LEXIS 1949 (Fed. Cir. Feb. 5, 2016). The primary focus of the *inter partes* review was to the “inflatable protrusions” claim term. *Id.* at 4-5, 21.

TriVascular, in seeking *inter partes* review, argued that the claim terms at issue here, notably means for injecting/inflating, a valve, and

inflatable cuff, should be interpreted as having ordinary meaning.

APPX265, Petition for *Inter Partes* Review, p. 6. The *inter partes* challenge to validity focused on the claimed protrusions and resulted in this Court affirming the PTAB's decision that the claims were valid over a previous patent owned by this same inventor. *TriVascular, Inc. v. Samuels*, 2016 U.S. App. LEXIS 1949, p. 20. That patent, US Patent No. 5,423,851, involved a similar stent, but instead of inflatable protrusions, it discloses employing a series of barbs that project outward to pierce the inside surface of a blood vessel in order to hold the stent in place in the blood vessel. *Id.*

### **III. The Accused Device**

The accused device made and sold by TriVascular employs a corresponding inflatable protrusion for holding the cuff in place and uses the same basic inflation system as shown in the patent. APPX1133, TriVascular's Claim Construction Brief, p. 1, fn. 1. An animation of the procedure for implanting the accused Ovation® System could be viewed on TriVascular's website at [http://www.trivascular.com/index.php?option=com\\_content&view=article&id=53&Itemid=170](http://www.trivascular.com/index.php?option=com_content&view=article&id=53&Itemid=170) but now is found at <http://www.trivascular.com/expanding-evar>. APPX1133, TriVascular's Claim Construction Brief, p. 1, fn. 1. Further, the primary way the accused cuff is deployed is by filling the cuff through a port while in situ in the aorta

with a hardening fluid, and maintaining the cuff in the inflated position by a seal valve engaged with the port until the material hardens in precisely the manner described in the patent. *Id.* In this embodiment of the patent, inflation is achieved by permitting a hardening fluid to enter the inflatable protrusions, thereby inflating the cuff, and waiting until the hardening fluid is set, after which the filling tube and syringe are removed from engagement with the port. APPX60, '575 patent, Col. 4:24-32. The accused device sold by TriVascular employs an identical inflatable protrusion for holding the cuff in the place and uses the same basic system as shown in the patent. See TriVascular animation, APPX1133, TriVascular's Claim Construction Brief, p. 1, fn. 1.

#### **IV. Proceedings in the District Court**

##### **A. The District Court's Claim Construction**

After claim construction briefing, the district court held a hearing on November 3, 2015. APPX1478, Transcript of Proceeding Held November 3, 2015, p. 1. On November 12, 2015, the District Court issued a Claim Construction Order. APPX1-21, Claim Construction Order.

The District Court's Claim Construction Order provides in pertinent part:

1. “means for injecting an inflation material into said cuff to inflate it”: The function is injecting an inflation material into said cuff to inflate it. The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve. APPX3, Claim Construction Order, p. 3.

2. “means for inflating the cuff with inflation material”: The function is inflating the cuff with inflation material. The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve. APPX4, Claim Construction Order, p. 4.

3. “a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation”: A valve, integral with the inflatable cuff, that has a moveable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation. APPX11, Claim Construction Order, p. 11.

5. “a valve”: A valve, integral with the inflatable cuff, that has a moveable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation. APPX11-2, Claim Construction Order, pp. 11-12.

6. “for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation”: A valve, integral with the inflatable cuff, that has a moveable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation. APPX12, Claim Construction Order, p. 12.

7. “inflatable and deflatable cuff of generally hollow cylindrical configuration”: A cuff, of generally hollow configuration, that has an inner surface and an outer surface and an inflatable and deflatable chamber in between the surfaces<sup>1</sup>. APPX16-7, Claim Construction Order, pp. 16-17.

### **B. The Stipulated Final Judgment**

Following the district court’s Markman ruling, the parties stipulated that Samuels cannot prove infringement in light of the court’s construction of certain terms. Thus, on December 17, 2015, the court entered final judgment on his patent infringement claims pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, leaving certain counterclaims pending in the district court. Samuels timely filed a notice of appeal on January 12, 2016.

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<sup>1</sup> Other terms of the patent were construed, but are not part of this appeal or germane to the judgment.

## **SUMMARY OF ARGUMENT**

This appeal concerns claim constructions that violate this Court's rules of claim interpretation. A construction may not import limitations restricting claims to particular embodiments or examples. The district court strayed from this core principle and issued a claim construction order that limits the claims to specific embodiments and examples from the specification, even to the point of excluding a preferred embodiment.

First, the district court explicitly and incorrectly incorporated details of the specification of a specific embodiment into the construction. The district court improperly believed the claim had to be construed to work in the narrowest method described in the specification, rather than interpreting the claims structure in their ordinary meaning and as taught specifically by the inventor himself. Second, the district court construed the claims in a manner that excluded a main, disclosed embodiment and the one used by TriVascular. Third, the district court construed the claim by incorporating method steps into an apparatus claim, thereby rendering the claim virtually unfringeable by a device manufacturer. Finally, the district court misapplied the canons of construction as they pertain to the "means for" claim elements to such a degree as to mandate inclusion of a structure

unnecessary to the stated function and included in other elements of the claim.

Specifically, the district court misconstrued the terms, “means for injecting,” “means for inflating,” “valve,” and “inflatable and deflatable cuff.” The Court construed “means for injecting/inflating” to mean “The function is inflating the cuff with inflation material,” and the structure is “an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve. APPX1-21, Claim Construction Order, pp. 3, 4. This construction goes astray because a valve is not a necessary component of the means for injecting/inflating.

The district court construed “valve” to mean “a valve, integral with the inflatable cuff, that has a moveable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation.” APPX11, Claim Construction Order, p. 11. This construction errs because the inventor used the term “valve” to include a circumferential valve without moving parts that permits inflation and seals the claimed stent.

The district court construed “cuff” to mean “a cuff of generally hollow configuration, that has an inner surface and an outer surface and an inflatable and deflatable chamber in between the surfaces.” The district

court noted in a footnote that this required the “entire” cuff to be inflatable. APPX16, Claim Construction Order, p. 16. The requirement of an inflatable chamber conflicts with other claims that specifically call for that limitation. Further, the characterization of the “entire” cuff being inflatable renders the claim language ambiguous and is contrary to the open-ended nature of the claim language “comprising.”

Lastly, the district court read into the claim aspects of a saline embodiment in such a way as to exclude the hardening fluid embodiment described in the patent and used by TriVascular. Further, the district court improperly construed the claim in such a manner as to render the claim indefinite and virtually unfringeable by a manufacturer by requiring method steps in an apparatus claim.

The district court’s claim constructions are incorrect and should be reversed. The corresponding judgment should be vacated and the case remanded so it can proceed under a proper claim construction.

## **ARGUMENT**

### **I. The District Court’s Claim Construction is Reviewed *De Novo***

Claim construction is a question of law that this Court reviews *de novo*. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 839 (2015) “The construction of claim terms based on claim language, the specification,

and the prosecution history are legal determinations.” *Trs. Of Columbia Univ. v. Symantec Corp.*, 2016 U.S. App. LEXIS 1718 (Fed. Cir. 2016). Here, the district court made no factual findings in its claim construction order but simply entered a stipulated final judgment of non-infringement based solely on the constructions. If the constructions are incorrect, the judgment must be vacated. *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277-78 (Fed. Cir. 2008).

## **II. Claims Are Given Their Ordinary Meaning Absent Lexicography or Express Disavowal of Scope**

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotations omitted). The standards for construing claims are well-established. “Claim terms are generally given their plain and ordinary meanings to one of skill in the art when read in the context of the specification and prosecution history.” *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). Indeed, there is a “heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time.” *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014) (quotations omitted).

*Phillips* explains why courts are admonished against importing limitations into claims: “if we once begin to include elements not mentioned in the claim, in order to limit such claim . . . we should never know where to stop.” 415 F.3d at 1312 (internal quotation and citation omitted). Courts therefore should not “at any time import limitations from the specification into the claims.” *Innogenetics N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quotation omitted). This is true even if a patent discloses only one embodiment. *See Phillips*, 415 F.3d at 1323 (“[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.”); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) “Absent a clear disavowal or contrary definition in the specification . . . the patentee is entitled to the full scope of its claim language.” *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004).

### **III. The District Court Erred in Construing the ‘575 Patent**

Claim 1 is illustrative of the independent claims and similar to Claims 14 and 23. The disputed terms on this appeal are highlighted:

1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:

a) **an inflatable and deflatable cuff of generally hollow cylindrical continuation** having a collapsible lumen, an inner surface, an inlet, an outlet and a friction enhancing outer surface, said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff, said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;

b) **means for injecting an inflation material into said cuff to inflate it;** and

c) **a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.** APPX61.

**A. The District Court Incorrectly Added Structure Not Necessary to the “Means for Inflating/Injecting” Terms**

The district court properly found, as both parties agreed, that the function in the means for claim terms was “injecting an inflation material into said cuff to inflate it” or “inflating the cuff with inflation material.” APPX3-4, Claim Construction Order, pp. 3-4, claims 1, 14 and 23. This simple function is accomplished with an inflation device such as a syringe as

shown in Figures 1 and 9a-9c (71, 117) and inflation tubing (61, 115). The Court then departed from this common sense structural limitation and included “a valve,” without describing which kind of valve was being included.

Putting aside this ambiguity in the construction, there is no reason to include any valve in the “means for injecting” or “means for inflating” because a valve is not the agent that causes the “injecting” or “inflating.” In fact, during the *inter partes* review, TriVascular asserted that the “means for” terms did not require a valve. APPX265-6, Petition for *Inter Partes* Review, pp. 6-7.

The district court recognized that the specification states “cuff 17 is inflated by way of an inflation syringe 71 with an inflation material 73,” and that it supports Samuels’ construction. APPX6, Claim Construction Order, p. 6; APPX48-62, ’575 patent. Other passages do as well. “In the configuration shown in FIG. 9b, inflation material 119 has been injected into stents 101 through 104 by manipulation of inflation syringe 117.” APPX61, Col 6: 16-18. Sufficient structure to perform the function is recited as “[t]he opposing end of inflation tubing 115 is connected to the inflation syringe 117 which is filled with inflation material.” APPX61 ‘575 Patent Col 6:2-4.

But the Court goes on to cite passages referring to “inflation” *and* “deflation” to support the added structure of a valve as being “necessary” to accomplish these functions. APPX1529, Transcript of Proceedings, November 3, 2015, p. 52. Again, the court cites to a single embodiment referring to a specific valve in concluding that the cuff is “inflated and deflated by means of a valve, indicated generally at 37,” and the court concluded that, when using a saline based fluid, somehow there can be no inflation without the leaflet valve. APPX7, Claim Construction Order, p. 7. Therefore, the Court improperly included the leaflet valve as part of the means for structure.

It is black letter law that only the structure required for performing the stated function is properly included in the claim construction:

Section 112, paragraph 6 does not permit incorporation of structure from the written description beyond that necessary to perform the claimed function. Structural features that do not actually perform the recited function do not constitute corresponding structure and thus do not serve as claim limitations.

*Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1369-70 (Fed. Cir. 2001) (citations omitted).

In the ‘575 patent, the leaflets or mitre valve are not necessary structure to inflating or injecting inflation material. Presumably, under its erroneous theory, the district court should have also included the port, fill

channels, walls of the inflatable protrusions, and all of the structure that holds the inflation material in the cuff as somehow part of the means for inflating or means for injecting. Indeed, the court rejected TriVascular's attempt to include "the mating end of inflation tubing, leaflets, an inflation port, and inflation material" without explanation, only stating that the valve is "at the core of its argument." APPX5, Claim Construction Order, p. 5, fn.

1. Of course, this demonstrates just the opposite and shows that such extraneous structure is unnecessary to the function of inflating, just as a valve is unnecessary. This is a recitation of excess structure not needed to perform the "function" of inflating, which is merely structure that causes inflation, *i.e.* the syringe and tubing.

The patent clearly shows two different valve configurations, including one employing a circumferential seal valve that permits the cuff to be inflated and maintains it in an inflated state while the hardening fluid solidifies. There is no need for a leaflet valve to accomplish this. Moreover, the valve is a separately recited element in the claims. Indeed, the dependent claims specifically refer to separating the "valve" from the inflation means. APPX62, *see, e.g.*, claim 8, '575 Patent. Further, the patent describes "[i]nflation tubing, not shown in this view, is located within catheter 87 and *is connected to stent 89 by the valve arrangement...*" indicating the valve is

not part of the means for inflating. APPX60, '575 Patent Col. 455-57.

Clearly the “means for” terms cannot include a valve if the valve is claimed as being “separated” from the inflation means and described as a separate component.

The district court cited *Saffran v. Johnson & Johnson*, 712 F.3d 549, 563 (Fed. Cir. 2013) to reject claim differentiation to “broaden a means-plus-function limitation beyond those structures specifically disclosed in the specification.” APPX7, Claim Construction Order, p. 7. But this doctrine is inapplicable here. In *Saffran*, a dependent claim referred to the same function as the independent claim. 712 F.3d at 563. Thus, the structures disclosed performed that single function in each claim and limit both claims. Here, the claim itself recites the valve as a separate element, and dependent claims 9 and 19 makes clear the valve is “separate” from the means for injecting/inflating. *Cf.*, *Wenger Mfg. v. Coating Mach. Sys.*, 239 F.3d 1225, 1234 (Fed. Cir. 2001) (claim differentiation applied). The dependent claims do not modify the same function in a way that conflicts with the independent claim to require the same structure.

The district court’s further reliance on *Intellectual Prop. Dev. Inc v. UA-Columbia Cablevision of Westchster, Inc.* 336 F. 3d 1308, 1320 n. 9 (Fed. Cir. 2003), citing *In re Kelley*, 305 F.2d 909, 915-16 (C.C.P.A.1962),

is likewise misplaced. In these cases, two structures described in the patent were either working together to perform the stated function or were a single item that performed multiple functions:

Where several sets of mechanisms cooperate to produce the desired result, a claim which recites these separate sets of mechanisms and their respective functions is not, ordinarily, objectionable as including an element twice because one element, *such as a power shaft, a drive gear, or a source of electric or other energy, is common to and cooperates with all such sets of mechanisms.*”

*In re Kelley*, 305 F.2d at 915 (emphasis added). This notion is inapplicable here because the means for inflating (or means for injecting) in no way requires or needs a valve with opposing leaflets – the disclosed mitre valve – to perform its function of inflation. Unlike *Intellectual Prop. Dev.* and *In re Kelley*, the claimed valve here is not performing two functions but only one that is completely separable from the inflation tubing and syringe.

The cases cited such as *Saffran* involved “means plus function” terms that are narrowly construed based on the specification and rejected the exclusion of additional terms claimed in dependent claims that further modified the same function. Here, the dependent claim informs the construction by distinguishing the structures that do the inflating or injecting from the valve, which is a separable component and is itself also separately claimed. Further, taking the district court’s logic to its conclusion, inflation

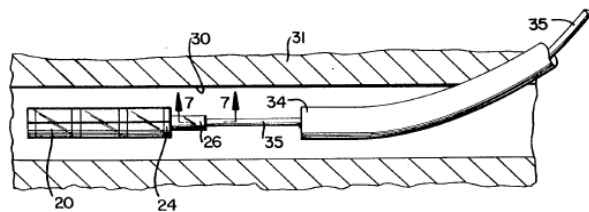
is accomplished not only by the syringe, the tubing and the valve, but also by the inflation channels, inflatable protrusions, and interior walls that hold the inflation material, because, by this logic, all are necessary to inflation. As stated in *Phillips* “we should never know where to stop.” 415 F.3d at 1312.

It should be noted that TriVascular’s invalidity contentions in the *inter partes* review are aligned with Samuels’ construction here. For example, TriVascular argued in the *inter partes* review that the “means for” clauses simply mean “inflation tubing connected to an inflation syringe filled with inflation material.” APPX266, Petition for *Inter Partes* Review, p. 7. TriVascular’s construction then should be adopted here since words of a claim should be construed in light of the specification, whether under a broadest reasonable interpretation, *TriVascular, Inc. v. Samuels*, 2016 U.S. App. LEXIS 1949, p. 7 (Fed. Cir. Feb. 5, 2016) or under an analysis according to *Phillips*, 415 F.3d at 1316.

Also, when it asserted invalidity contentions for the claim term “means for injection inflation material into said cuff to inflate it,” TriVascular stated: “The structure corresponding to the means for injecting includes a syringe for injecting an inflation material and an inflation port.” APPX285-317, Petition for *Inter Partes* Review, pp. 26-58. Citing a

prior art reference, it alleged this element is described by:

“[I]llustrated in FIGS. 5 and 6. It can be seen that prosthesis 20 is connected, by virtue of its filling port 26, to a catheter 35. It is preferred that catheter 35 be flexible and hollow so that it may deliver fluid from outside of the patient's body to inflation channels 24 in the intravascular prosthesis. The end of flexible catheter 35 outside of the patient may be connected to a fluid source (not shown) so that fluid may be delivered, preferably, under pressure, to the prosthesis inside the blood vessel.”



*Fig. 5*

Figure 5, U.S. Patent No. 4,705,517, DiPisa, Jr., Issued November 10, 1987.

APPX1422-3, Plaintiff's Claim Construction Reply Brief, pp. 5, 6. But “the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses...[a] patent may not, like a ‘nose of wax,’ be twisted one way to avoid anticipation and another to find infringement.”

*Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). TriVascular may not assert one claim construction to invalidate the claims, and then another to avoid infringement.

Finally, the Court improperly includes “a valve” without stating which kind of valve is included in the “means for” claim terms. This introduces indefiniteness and ambiguity in the claims that must also be corrected if the

valve structure is to remain at all. The Court essentially acknowledges that, even under its improper construction, the circumferential seal valve would accomplish the sealing function when using hardening fluid. APPX57, '575 patent, Fig. 9b. Yet this misses the point. The valve – whether a seal valve, leaflet valve, or some other kind – is not necessary to the inflating function any more than the channels, port, or the entire configuration of the device are. The court's approach is analogous to describing “means for inflating a basketball using a tire pump” to require the basketball itself to be part of the “means for inflating” to accomplish its own inflation. The proper construction for the structure of this “means for” term is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71,117) and inflation tubing (61, 115).

**B. The District Court Incorrectly Limited “Valve” to One Narrow Exemplary Embodiment**

**1. The district court improperly imported the specification into the claim construction**

As is readily apparent from the Court's comments at the hearing and its decision, the Court construed the apparatus claims to include method steps in order to make it “work” with a narrow embodiment. The Court first paid lip service to the notion that embodiments “should not be imported into the claims as limitations,” but then did precisely that. APPX3, Claim

Construction Order, p. 3. Indeed, the court cited the two exceptions to that rule not to import the specification into the claims, i.e., a patentee acts as its own lexicographer or expresses a clear disavowal of claim scope, and found that *neither* exception applied. The Court then cited to a disclosed embodiment involving a saline-based fluid as support for its narrow reading of the claim terms, reasoning that certain structural limitations were required in that embodiment after removal of inflation tubing. Otherwise the “material [saline] will, in effect ‘leak out.’” APPX7, Claim Construction Order, p. 7. The Court further compounded this error by interpreting a second embodiment using a hardening fluid to require that the same structure was needed to prevent “leakage” because “hardening is a process that takes at least some time.” *Id.* Thus, the Court required that the valve recited in the claims must permit entry of inflation material and then “actually seal[] the cuff itself.” APPX13, Claim Construction Order, p. 13. The Court concluded that the valve has to “work” in a sequenced fashion according to the method of use rather than serve as a structure capable of performing as a valve as described in the patent.

This is all the more troublesome in that the patentee described *several* “valves,” including a circumferential seal valve that permits inflation and prevents deflation while using a hardening fluid. If anything, the term

“valve” includes two completely separate versions as defined by the patentee—circumferential valve and a mitre valve. Any construction should have encompassed both of these. In certain embodiments, the only valve that comes into play is the circumferential valve, not the optional leaflet valve, which will be frozen in position while the fluid hardens.

The district court construed the term “valve” as part of a broader statement in the claim referring to capability, not structure. By doing so, it explicitly interpreted the apparatus claim not for its structure but according to how it operates in one of the preferred embodiments. It also rendered the claim unenforceable by a manufacturer or seller of the device. Under the court’s construction, infringement can only be assessed depending on how the device is used by the end-user. That is, movable parts of a valve must open and close, and only the end-user, not the manufacturer, would cause this to occur. This is improper on its face and undercuts the clear teaching of the patent, the terms used, and proper claim construction.

## **2. Valve has a plain meaning in this patent to one of ordinary skill in the art**

The term “valve” has a basic meaning and, in this patent, at least three different exemplary embodiments of that term are disclosed and used. The term is generic and was used by this inventor in this technology to mean, among other things, (i) a circumferential fitting that engaged inflation tubing

to the port of the cuff, (ii) a separate mitre valve inside the port, and (iii) a combination of the two. This was outlined in the patent, and constitutes the language used by the inventor to disclose his invention. “Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004). Here, the patentee did just the opposite – he used a broad term and disclosed several possible embodiments as support, but the court erroneously construed the term based on the narrowest embodiment.

The district court disregarded the various uses of the term that appear in the ‘575 patent and instead sought to define the term in a way that only covers what is explicitly shown in the drawings and would be employed only in the case of the most comprehensive embodiment of the invention involving saline. Yet as this Court has stated:

Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. In examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims. Applying these principles to claim 14, this court concludes the trial court's construction was unduly narrow.”

*Varco, L.P. v. Pason Sys. USA Corp.*, 436 F.3d 1368, 1372-1373, (Fed. Cir. 2006) (citations omitted).

Samuels' construction of the term "valve" is supported by the patent and ordinary meaning. The specification shows a number of valves and uses the term in at least two different and broad ways. APPX47-62; '575 patent, *see, e.g.*, Col. 2, lines 45-48; Col. 4: lines 8-65; Col. 6: lines 10-16; 23-31; Figures 1, 4a-4b, 9a-9c; Claims 8 and 9; and APPX302, TriVascular Petition for *Inter Partes* Review pp. 43; APPX1126-8, JDP Decl. Exh N. The patent clearly expresses the potential use of a wide range of valves and sets forth multiple, exemplary valve arrangements.

For instance, the patent references a valve 43, shown in Figure 4a, as a circumferential seal valve that permits the device to be inflated and always prevents backflow upon inflation. The patent also discloses a valve 45, shown in one embodiment as a mitre valve, which is normally held open, in use, by the inflation or fill tube but can close to prevent backflow upon premature removal of the inflation tube, or even remain open upon hardening of the inflation material. The district court states that "there is nothing in the '575 patent to indicate that the breakaway valve itself seals," even though the patent explicitly contradicts this by showing it to be the operative valve during and after inflation, since the optional leaflets are

spread open and non-operative. *See, e.g.*, APPX51, ‘575 Patent, Fig. 4a, Col. 4:21-23 (“When in this configuration, circumferential notch 65 engages circumferential rim 55 so as to secure inflation tubing within inflation port 39”); *see also, infra*, pp. 30-32 (discussing the known prior art understanding of this type of valve and how it maintains the inflated cuff) .

Still, the patentee clearly used the term “valve” broadly in connection with the invention, as evidenced by both of the exemplary valves referenced above being the subject of dependent claims, thereby mandating a broader scope for the other claims. The claim cannot be limited to the specific embodiment shown in the patent and in this situation cannot require both valves to be present in the independent claims. This is directly contrary to basic and fundamental patent law and should be rejected.

One need go no further than the patent in suit, and Samuels’ prior patent, U.S. Patent No. 5,423,851 (which was at the heart of the successful *inter partes* review confirming these claims as valid) to teach one of ordinary skill that a valve with no moving parts is contemplated by this invention. The patent in suit clearly teaches the use of a breakaway or seal valve as a mechanism for maintaining the stent in an inflated condition. In the situation involving a hardening agent, the patent describes: “The stent is inflated with an inflation material that may contain a hardening agent. A

valve, which is integral with the stent, allows it to be sealed in an inflated condition after it is placed in the proper position.” APPX59, ‘575 patent, Col. 2:45-48. The valve that maintains the inflation while the material hardens is the breakaway valve 43, not the mitre valve, which is hardened in an opened position if present at all. It never closes, as the patent describes, because “after cuff 17 has been installed and inflated, the material 73 hardens over time to permanently affix stent 5 within the tubular structure....” APPX60, ‘575 patent, Col. 4:41-44<sup>2</sup>.

Indeed, one of ordinary skill is well versed in this use of a non-moving parts valve simply by reference to Samuels’ previous ‘851 patent. The ‘851 patent states very clearly:

It is within the scope of the present invention to utilize a pullaway detachable valve in place of duck bill [mitre] valve 20. When a pullaway valve is used, the cuff 10 is inflated and deflated at low pressure to confirm its position and then is fully inflated at a higher pressure. After the inflation material 34 inside the cuff is slightly hardened, the operator of the device pulls on the inflation tubing to break connection with the cuff where the lumen is thinnest. Thus, the medical device is fully secured to the vessel wall.

APPX1426 quoting Samuels ‘851 Patent, Col. 3:14-23.) Prior art that sheds

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<sup>2</sup> The accused TriVascular device instructs the operator to wait 14 minutes while the hardening agent sets up *before* removal of the fill tube from the port. Video at 4:13-45, <http://www.trivascular.com/home> and <https://www.youtube.com/embed/9xjVGZOviz8?rel=0>

light on the meaning of a term “can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning”). *Arthur A. Collins, Inc. v. N. Telecom, Ltd.*, 216 F.3d 1042, 1045 (Fed. Cir. 2000). Here, we have the identical inventor using common terms in the prior art and patent in suit.

### **3. Extrinsic evidence supports Samuels’ broad plain meaning**

The extrinsic evidence fully supports Samuels’ broad construction as well. For example, TriVascular uses the term in its own patent to refer to a valve 16 employed in the medical environment having a hole 36 that remains nominally open in use. APPX962-79, *see* U.S. Patent 7,901,379 Col. 7:6 – Col. 10:57 and Figures 1-8. Similarly, U.S. Patent 8,801,769 in its entirety and U.S. Patent 4,460,018 in its entirety, show a valve 10 that support this construction. APPX1070-91. Further, U.S. Patent Nos. U.S. 5,693,088 and U.S. 5,665,117, as described in the *inter partes* review petition on page 43, also support a broad reading of the term. APPX981-98, U.S. Patent 5,693,088 (valve 58, Figure 4); APPX1000-15, U.S. Patent 5,665,117 (self-sealing port 80, Figure 9); APPX302, Petition for *Inter Partes* Review claim chart, p. 43 valve term.

Basic dictionary definitions confirm this broad and reasonable interpretation. For example the *American Heritage Dictionary of the English Language*, online version, states that a valve is “any of various devices that regulate the flow of gases, liquids, or loose materials through piping or through apertures by opening, closing or obstructing ports of passageways.” See [www.ahdictionary.com](http://www.ahdictionary.com), search term valve. Dictionary.com states a “valve” may be “any device for halting or controlling the flow of a liquid, gas, or other material through a passage, pipe, inlet, outlet, etc.” As the definitions suggest, a valve may be used to regulate flow by a variety of mechanisms and does not require in all cases that it stop or start flow. Dictionary definitions may not always be definitive, but here they illustrate that a generic term like “valve” may be used broadly and to its fullest extent in the patent. And clearly it was not an element that was germane to patentability.

**4. The district court’s claim construction denies Samuels the scope of his invention and disregards claim differentiation.**

The ‘575 patent specifically discloses several valves, including one with no moving parts that nonetheless performs in an embodiment of the invention. The district court’s construction therefore denies the inventor even the scope of valves explicitly taught and described in the specification.

It appears to simply take a figure of the patent and require that single embodiment to be used for the construction. But there is nothing in the file history or the specification that would arbitrarily limit the term this way.

Indeed, as noted above, the patent itself identifies three valve arrangements by way of example: a mitre valve, a circumferential breakaway valve, and a combination of the two. The district court's construction would preclude the plain meaning of the term by requiring that two valves be present in the independent claims. This runs afoul of basic canons of construction and disregards the clear claim differentiation between claim 1, for example, and claim 9 that adds that the "valve" is of a "breakaway design." It is only at the point of claim 9 that the inventor limits the invention to the disclosed breakaway valve; claim 1 was intended to cover all valves, including the breakaway valve and others. As interpreted by TriVascular, the mitre valve it requires in claim 1 cannot be a breakaway design as further claimed in claim 9; yet such a breakaway valve can itself perform the functions of permitting and preventing deflation. As this Court has observed, "[a] claim construction that excludes a preferred embodiment . . . is rarely, if ever correct." *Vitronics Corp. v. Conceptiontronic*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

Dependent claim 8 recites a mitre valve as an additional limitation. But under the district court's construction, claims 8 and 1 would have the same scope, further illustrating the court's error. *See Dow Chem. Co. v. United States*, 226 F.3d 1334, 1341-42 (Fed. Cir. 2000) (independent claim receives broader scope than dependent claim to avoid rendering dependent claim redundant); *see also TurboCare Div. of Demag Delaval v. General Elec.*, 264 F. 3d 1111, 1123 (Fed. Cir. 2001) (claim terms should not be read to contain limitation "where another claim restricts the invention in exactly the [same] manner").

The district court's misunderstanding of the patent was revealed at the Markman hearing. "[I]f you use a saline-based fluid," the court commented, "which is one of the alternatives that's called out here, you have to have some kind of valve, because that's going to leak out right." APPX1494-5, Transcript of Proceeding Held November 3, 2015, pp. 17, 18. The Court then noted that, due to the specification, "because it said saline-based fluid or material that contains a hardening agent[,] [t]hat means it could be either, and you can't have the former without some kind of a valve." APPX1495, Transcript of Proceeding Held November 3, 2015, p. 18. Thus, even after recognizing dependent claim 8 calls for a mitre valve, the court nonetheless interpreted the broader valve term to require moving parts generally without any support in the specification for this definition other than the single embodiment showing a leaflet valve.

**5. The district court imposed an unreasonable limitation by construing the phrase “thereafter” in a restrictive manner**

The court also seemed to conclude that the term “thereafter” in the broader rendition of the claim requires that sealing occur *after* the completion of inflation, not while inflation is ongoing. After recognizing that, “if you didn’t have a breakaway valve, the stuff would leak out as soon as you’d put it in,” the Court proceeded to construe the term “thereafter” as requiring sealing *after* complete inflation and removal of the fill tube. APPX1506-7, Transcript of Proceeding Held November 3, 2015, pp. 29-31. See also APPX13, Claim Construction Order, p. 13 (according to the district court, “[t]he use of the word ‘thereafter’ is important.”)

Not only is this a distinction without a difference, it is explicitly contrary to the teaching of the patent when using hardening agents. Nothing in the patent limits hardening to a particular time period, nor does the patent suggest the circumferential valve fails to create a seal while using the embodiment until the fluid hardens. Indeed, the Court said as much when analogizing to the inflation of a basketball: “If you didn’t have a breakaway valve and the circumferential ring to seal it while you’re filling it up...it’s like trying to fill up a basketball with air leaking out at the same time, you get nowhere.” APPX1507, Transcript of Proceeding Held November 3,

2015, p. 30. This is precisely the point. The circumferential seal valve permits inflation and thereafter seals. Nothing more is claimed or required. Obviously, after the material hardens, the inflation tubing is removed and a seal is no longer needed.

The District Court’s construction additionally introduces a method step into the claim by requiring that the valve operate in some timed sequence, rather than as explicitly described, during inflation. By interpreting the words after recitation of a “valve” to require a certain function, the Court has essentially turned this clear structure limitation into a method limitation requiring method steps that occur in a required sequence, including removal of a component of the claimed apparatus—the fill apparatus.

A proper construction that fits the specification – which describes various valves, including ones with no moving parts – is to construe the term as simply any structure that affects fluid flow. This is the normal broad dictionary definition and the one that encompasses the specific “valves” described in the patent.

The circumferential seal valve only works if it prevents the material from leaking out during and after inflation. As the Court apparently recognized, a basketball cannot inflate if there is nothing keeping the air

from leaking out. APPX1507, Transcript of Proceeding Held November 3, 2015, p. 30. There is nothing in the structural claim that requires the inflation tubing to be removed; indeed, it is recited as part of the structure in the claimed device, means for inflating/injecting. The device claim has to stand on its own without regard to how the device is used or employed. As apparatus claims, only the claimed *structure* is relevant to claim construction, not *functions* the structure may be capable of. “[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) (emphasis in original). By contrast, the district court’s construction stems from its view of how the device will be used, and limitations were added to the construction to make it “work” with saline, an embodiment not even commonly used, rather than simply deriving from the claim terms themselves.

Interpreting the term “thereafter” to limit the valve structure and construe it a certain way conflicts with the plain meaning of the term itself. The hardening time period of the inflation fluid “thereafter” cannot be a distinction between infringement and non-infringement. “Construing a non-functional term in an apparatus claim in a way that makes direct infringement turn on the use to which an accused apparatus is later put

confuses rather than clarifies, frustrates the ability of both the patentee and potential infringers to ascertain the propriety of particular activities, and is inconsistent with the notice function central to the patent system.” *Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1090-91, (Fed. Cir. 2009). In *Paragon*, the Court rejected a construction that specified an amount of time for certain real time reporting for a sports watch, depended on the activity. “The problem with construing ‘displaying real-time data’ as used in the claims of the ’759 patent to preclude ‘contextually meaningful delay’ is that such a construction injects a use limitation into a claim written in structural terms.” *Id.* at 1090. As the *Paragon* Court noted: “If the district court’s construction were correct, then the same apparatus might infringe when used in one activity, but not infringe when used in another. For example, consider a device that had a delay of thirty seconds between the time at which it calculated a user’s velocity and the time that it displayed it. *Id.* ...[A]ny use of a device that meets all of the limitations of an apparatus claim written in structural terms infringes that apparatus claim.” *Id.* at 1091.

As to the construction of the terms “for permitting” and “thereafter sealing,” these merely recite capability. They do not, by themselves, add or require structural limitation. This construction is based on the claim language itself and the rules of claim construction, and is reinforced by the

language in the specification at APPX60, '575 patent, Col. 4: lines 8-65; APPX49, '575 patent, Fig. 1; APPX51-2, '575 patent, Figs. 4a-4b; APPX56-8, '575 patent, Figs. 9a-9c. As stated in *Finjan, Inc. v. Secure Computing Corp.*:

As we have cautioned, in every infringement analysis, the language of the claims, as well as the nature of the accused product, dictates whether an infringement has occurred. Accordingly, we have held that, to infringe a claim that recites capability and not actual operation, **an accused device 'need only be capable of operating' in the described mode.** Thus, depending on the claims, an accused device may be found to infringe if it is reasonably capable of satisfying the claim limitations, even though it may also be capable of noninfringing modes of operation.

626 F.3d 1197, 1204 (Fed. Cir. 2010) (emphasis added) (citations and quotations omitted). Correspondingly, if an accused device need only be capable of operating as claimed for purposes of infringement, the structure in the claim need only be capable of operating as claimed for claim construction purposes. Thus here, the valve need only be capable of performing the claimed function and not need actually do so.

For further illustration, consider valves 43 and 45, discussed above. Valve 43 always prevents backflow upon inflation and permits the device to be inflated in the first place. As for mitre valve 45, when the cuff is inflated with hardening material, the material solidifies, leaving the mitre valve locked in an open position. Then, the fill tube is removed, rendering the

mitre valve superfluous. However, in some situations, the mitre valve may operate to prevent backflow upon removal of the inflation tubing. As such, the mitre valve is “capable of” preventing backflow, though it does not normally do so. In each case, the valve is capable of not stopping inflation and of stopping inflation, thereby preventing deflation. Indeed, the seal valve around the inflation tubing, if not present, would result in the device not inflating since the material could flow around the tubing, causing the rings not to inflate. As previously noted, the circumferential valve “secures inflation tubing 61 within inflation port 39.” APPX60, ’575 patent, Col. 4: 21-23. Without that valve, the cuff would deflate.

Even so, the circumferential valve does “permit” inflation, which only means that it does not stop inflation, and by its very stated purpose, it also thereafter seals the cuff. The Court’s construction is limited to a valve that stays in the body and only seals at some later undetermined time upon removal of the means for inflation, though this is nowhere required by the specification or use of the device. Indeed, the claim is to the entire device with the “means for inflating,” *i.e.*, the syringe and tubing intact with the cuff. In some circumstances, the means for inflating may remain attached to the cuff and the entire structure can be removed intact.

It bears repeating that in an embodiment using hardening fluid, which is the one actually used by TriVascular and the one used when leaving part of the claimed device in the body, there is no need for a leaflet or mitre valve. The only valve needed is the circumferential valve which permits the inflation to occur, prevents deflation while the material hardens, and then becomes irrelevant. Nothing in the claim language requires the valve to seal one second, one minute, or two hours later. Nor does this preferred embodiment even need an internal leaflet valve.

A proper construction of “for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation” is “capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered the cuff to prevent deflation.” By its narrow construction, the district court has rendered the invention meaningless because the very thing Samuels invented – an inflatable protrusion cuff – is not infringed even when using the very circumferential seal he disclosed and claimed. The result is that a fully valid patent which survived *inter partes* review and appeal is essentially rendered immune from infringement by a device manufacturer who uses the exact

embodiments disclosed in the patent. It is hard to imagine a more anomalous outcome.

**C. The District Court Incorrectly Narrowed the Claimed Cuff and Introduced Ambiguity into the Construction**

The proper construction of the term “inflatable and deflatable cuff of generally hollow cylindrical continuation [sic configuration]” is plain meaning, that is, a “cuff of generally hollow configuration.” Samuels’ construction is that of ordinary meaning supported by the specification. APPX47-62, ’575 patent Col. 2: lines 33-46; Col. 3: lines 27-32; 42-53; and Figures 1, 4a-4b, 5a-5d, 8, 9a-c. The Court inexplicably added the concept of an inflatable chamber to this particular term in claim 1, though it cannot be found there and is only specifically recited in claims 14 and 23. Further, the Court appears to require that the entire cuff be inflatable.

Adding limits to a claim is error. As stated in *Phillips v. AWH Corp.*:

Because the patentee is required to “define precisely what his invention is,” the Court explained, it is “unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.” (“the claims measure the invention”); (“if we once begin to include elements not mentioned in the claim, in order to limit such claim ..., we should never know where to stop”); (“the claims made in the patent are the sole measure of the grant”).

415 F.3d 1303, 1312 (Fed. Cir. 2005) (citations omitted).

In this case, the district court's conclusion that two distinctly worded, independent claim terms should be interpreted to have the exact same meaning, though one boasts an additional structural limitation, defies standard patent claim construction and makes no sense. Claim 1 recites an inflatable cuff that does not require an inflatable chamber. The inflatable cuff of claim 1 may be inflated by inflation of just the protrusion(s) which are part of the "cuff" as claimed. In other words, if part of the cuff inflates, (*e.g.*, the one or more inflatable protrusions), an inflatable cuff is established. Claims 14 and 23 add the further element of an inflatable chamber. True, a claim drafter may use different terms to define the same subject matter, but "differences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Philips*, 415 F.3d at 1314; *accord Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380-81 (Fed. Cir. 2006) (discussing doctrine of claim differentiation as applied to independent claims).

The court repeatedly made the mistake of importing into the claim construction structure associated with specific embodiments and/or the written description. But this way of reading a patent flies in the face of precedent. "[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining

the claims to those embodiments.” *Inline Plastics Corp. v. EasyPak, LLC*, 799 F.3d 13264, 1369 (citing *Phillips*, 415 F.3d at 1313); *see also Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 807 (Fed. Cir. 2007) (“transverse holes” need not be construed as perpendicular despite repeatedly describing them as such in the specification); *Comark Communs v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998). An applicant is not required to describe in the specification every conceivable and possible future embodiments of his invention. *See SRI Int’l v. Matsushita Elec. Corp of Am.*, 775 F.2d 1107, 1121 (“that claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims”). By the same token, the claims cannot be limited to just disclosed embodiments, particularly as the inventor need only disclose a single preferred embodiment. It has been repeatedly held that independent claims cover a scope broader than a preferred embodiment. *See RF Delaware., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1264-65 (Fed. Cir. 2003) (“patentee clearly set a different boundary by claiming a filter bed with only “a” filter layer in claim 1 and a filter bed with only a filter layer and a flocculation layer in claim 7”).

The district court makes reference to the cuff as being expressly described as “inflatable and deflatable,” and then asserts without citation that

“there must be a chamber within the cuff that can be filled with inflation material.” APPX17, Claim Construction Order, p. 17. The court goes on to speculate that Samuels could have used the term “expandable” rather than inflatable, and thus the cuff must be separately inflatable from the “inflatable protrusions,” though the cuff “comprises” the inflatable protrusions. *Id.* It rejected Samuels’ argument that the cuff may be inflatable due to the inflation of the protrusions, and instead determined that the “cuff” is the entire structure and thus must mean “the entire structure is inflated.” APPX17, Claim Construction Order, p. 17.

The court’s view unduly limits the language to an inflatable chamber, present in independent claim 23 but not independent claim 1. What’s more, it introduces another ambiguity in that it seems to require the claim to be a cuff “consisting” of an inflatable chamber such that any additional structure, even a flap of material, would render it not “entirely inflatable.” There was no reason to include this construction, and to the extent it means the cuff must be “entirely inflatable,” it is erroneous. The claim is clearly open-ended, using the common phrase “comprising,” and there is no support for concluding that the cuff be *entirely* inflatable.

The Court’s flawed logic that, since there may be only one inflatable protrusion, the “cuff would consist of simple ring and not a cylinder,” is also

unsupported by the language of the claim or the specification. APPX17-8, Claim Constriction Order, pp. 17-18, fn. 9. Nowhere does the invention require the cuff to be a particular length of elongated tube, and clearly a large inflatable protrusion would itself be sufficient in some situations to form a band or cuff and act as a claimed stent. Again, the Court has imported its views on one specific use into the claimed structure.

The district court's approach is also contradicted by this Court's position in *TriVascular, Inc. v. Samuels*, 2016 U.S. App. LEXIS 1949 (Fed. Cir. Feb. 5, 2016) where the Court referenced the '575 patent and states: "These 'inflatable and deflatable cuffs' are depicted by the number 17 in Figure 1 of the '575 patent below, and can be inflated by introduction of a fluid into each of the 'circumferential ridges' 25." Notably, this Court held that "a key point of distinction between the '575 patent and the prior art is that the '575 patent teaches the use of inflatable, circumferential ridges that do not penetrate the vessel wall." *Id.* at 17. It was the reason the patent was allowed and this Court affirmed validity in the *inter partes* review. Yet by unduly narrowing the claims, the district court has undercut the plain meaning of basic elements in a way that nullifies the inventive feature of this patent.

The inflatable cuff described and claimed may be a structure having a single inflatable protrusion that itself inflates and creates a stent according to the broad terms of the patent. Any requirement that *the entire structure* of the stent be “inflatable” is in error and incorporates into the claim language a specific structure shown in a drawing and nullifies the open-ended nature of the claim. The correct construction is plain meaning *i.e.*, “cuff of generally hollow configuration”.

### CONCLUSION

The district court’s claim construction rulings should be reversed. Because Samuels stipulated to a final judgment of non-infringement based solely on that court’s incorrect claim constructions, this Court should vacate the judgment and remand for further proceedings in view of the correct claim constructions for the terms as listed below:

1. “means for injecting an inflation material into said cuff to inflate it” (claim 1), “means for inflating the cuff with inflation material” (claim 14), and “means for inflating the plurality of cuffs with inflation material” (claim 23) should all be construed to have the following structure: an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71,117) and inflation tubing (61,115) and all equivalent structures.

2. The term “A valve” should be construed to cover any structure that affects fluid flow.

3. The term “for permitting entry of the inflation material from the means for injecting/inflating and thereafter sealing said cuff to prevent deflation” (all claims) should be construed to mean “capable of not stopping inflation material from entering the cuff from the means for injecting/inflating and capable of stopping inflation material from leaving the cuff after the injection material has entered the cuff to prevent deflation.

4. “A valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation” (claim 1) and “A valve integral with the inflatable cuff/one of the plurality of cuffs for permitting entry of the inflation material from the means for inflating ... and thereafter sealing the cuff to prevent deflation” (claims 14 and 23) should *not* be construed in its entirety or should be construed as “Any structure that affects fluid flow, formed or combined as a unit with the cuff, and is capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered the cuff to prevent deflation.”

5. The term “inflatable and deflatable cuff of generally hollow cylindrical continuation” should be construed to cover “a cuff of generally hollow cylindrical configuration which is capable of being inflated and deflated.” The term should not be read to require the entire cuff to be inflatable or a separate inflatable chamber.

Dated: March 10, 2016

Respectfully submitted,

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# **ADDENDUM**

### **ADDENDUM TABLE OF CONTENTS**

<b>File Date</b>	<b>Dkt No.</b>	<b>Description</b>	<b>Appx. No.</b>
11/12/2015	92	Claim Construction Order	Appx1
12/17/2015	98	Final Judgement	Appx22
10/05/2015	82.3	Exhibit 2 – U.S. Patent No. 6,007,575	Appx47

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

SHAUN L.W. SAMUELS,

Plaintiff,

v.

TRIVASCULAR CORPORATION, et al.,

Defendants.

Case No. 13-cv-02261-EMC

**CLAIM CONSTRUCTION ORDER**

Docket Nos. 81-82, 84

Plaintiff Shaun L.W. Samuels is the owner of the '575 patent which concerns an inflatable stent. Dr. Samuels has accused Defendant TriVascular Corporation and several individuals affiliated with the company of patent infringement (collectively, "TriVascular"). Currently pending before the Court are the parties' competing briefs regarding claim construction of the '575 patent.

**I. FACTUAL & PROCEDURAL BACKGROUND**

As noted above, the '575 patent concerns an inflatable stent. For the most part, a representative claim from the patent is claim 1. Claim 1 reads as follows:

1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:

a) **an inflatable and deflatable cuff of generally hollow cylindrical continuation** having a collapsible lumen, an inner surface, an inlet, an outlet and a friction enhancing outer surface, said friction-enhancing outer surface featuring **inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff, said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving** in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;

b) **means for injecting an inflation material into said cuff to inflate it;** and

c) **a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.**

'575 patent, claim 1 (emphasis added). Terms to be construed include those bolded above.

## II. DISCUSSION

### A. Legal Standard

Claim construction is a question of law to be determined by the Court. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (“hold[ing] that in a case tried to a jury, the court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim”). “The purpose of claim construction is to ‘determin[e] the meaning and scope of the patent claims asserted to be infringed.’” *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008).

Words of a claim are generally given their ordinary and customary meaning, which is the meaning a term would have to a person of ordinary skill in the art after reviewing the intrinsic record at the time of the invention. “In some cases, the ordinary meaning of claim language . . . may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” However, in many cases, the meaning of a claim term as understood by persons of skill in the art is not readily apparent.

*Id.*

Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” Those sources include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.”

*Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). As a general matter, extrinsic evidence such as dictionaries and expert testimony is considered less reliable than intrinsic evidence (*i.e.*, the patent and its prosecution history). *See id.* at 1317-19 (noting that “extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent

claim scope unless considered in the context of the intrinsic evidence”).

Generally, embodiments from the specification should not be imported into the claims as limitations. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1369 (Fed. Cir. 2012) (“We do not read limitations from the specification into claims.”). “There are only two exceptions to this general rule: (1) when a patentee sets out a definition and acts as his own lexicographer, or (2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution.” *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

B. “means for injecting an inflation material into said cuff to inflate it” and “means for inflating the cuff with inflation material”

Dr. Samuels’s Proposed Construction	TriVascular’s Proposed Construction	Court’s Construction
<b>“means for injecting an inflation material into said cuff to inflate it”</b>		
<b>Function:</b> The function is injecting an inflation material into said cuff to inflate it.  <b>Structure:</b> The corresponding structure is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71, 117) and inflation tubing (61, 115).	<b>Function:</b> The same.  <b>Structure:</b> The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117) containing an inflation material; inflation tubing (61, 115) with a mating end (63) that opens a valve by separating opposing leaflets (51, 53) that are in an inflation port (39, 123) to inflate the cuff.	<b>Function:</b> The function is injecting an inflation material into said cuff to inflate it.  <b>Structure:</b> The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve.

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“means for inflating the cuff with inflation material”		
<b>Function:</b> The function is inflating the cuff with inflation material.  <b>Structure:</b> The corresponding structure is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71, 117) and inflation tubing (61, 115).	<b>Function:</b> The same.  <b>Structure:</b> The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117) containing an inflation material; inflation tubing (61, 115) with a mating end (63) that opens a valve by separating opposing leaflets (51, 53) that are in an inflation port (39, 123) to inflate the cuff with the inflation material.	<b>Function:</b> The function is inflating the cuff with inflation material.  <b>Structure:</b> The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), and a valve.

The first term (“means for injecting an inflation material into said cuff to inflate it”) can be found in, *e.g.*, claim 1(b). The second term (“means for inflating the cuff with inflation material”) can be found in, *e.g.*, claim in 14(c).

Both parties agree that the two terms should be considered together. Both parties also agree that the above terms are means-plus-function limitations. Means-plus-function limitations were, at the time, governed by paragraph 6 of 35 U.S.C. § 112, which provided as follows:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112 (1999).

In enacting this provision, Congress struck a balance in allowing patentees to express a claim limitation by reciting a function to be performed rather than by reciting structure for performing that function, while placing specific constraints on how such a limitation is to be construed, namely, by restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof.

*Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347 (Fed. Cir. 2015) (en banc).

Here, the parties do not have a dispute as to what the claimed functions of the means-plus-function elements are – *i.e.*, injecting an inflation material into the cuff to inflate it and inflating the cuff with inflation material. (As indicated by the above, the functions for the two elements are essentially the same.) Rather, the parties dispute what the corresponding structure for each function is. Dr. Samuels argues that, in each case, the structure that performs the function is simply a syringe and inflation tubing. In response, TriVascular contends that the structure is not just a syringe and inflation tubing but also includes a valve.<sup>1</sup>

In his papers, Dr. Samuels contends that a valve should not be part of the structure because there is a *different* claim element (*e.g.*, claim 1(c) instead of claim 1(b)) that addresses a valve. *See* Op. Br. at 9. But as TriVascular argues in its papers, one structure can perform multiple functions, not just one – *i.e.*, nothing bars a valve from performing the function of “permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation” (claim 1(c)) and *also* performing the function of inflating the cuff with inflation material (claim 1(b)). This makes practical sense. In addition, TriVascular has support for its position from *Intellectual Property Development, Inc. v. UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308 (Fed. Cir. 2003) (hereinafter *IPD*).

In *IPD*, one element in the claim at issue was “*light beam demodulation means* at said reception position responsive to said *photo-sensitive detector means* to convert said light beam

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<sup>1</sup> TriVascular’s construction also refers to, *e.g.*, the mating end of inflation tubing, leaflets, an inflation port, and inflation material, *see* Resp. Br. at 5, but at the core of its argument is the valve.

1 into demodulated high frequency carrier radio wave signals modulated with video broadcast  
2 signals.” *Id.* at 1312 (emphasis added). According to the district court,

3 since the claim language requires that the “photo-sensitive detector  
4 means” and the “light beam demodulation means” be “responsive  
5 to” each other, they could not, as urged by [the plaintiff], be  
6 contained in the same structure, i.e., the photo-sensitive detector.  
Otherwise, according to the court, the words ‘responsive to’ would  
be read out of the claim.

7 *Id.* at 1318. The Federal Circuit disagreed with the district court, stating as follows: “Contrary to  
8 [the defendant’s] argument, we see no reason why, as a matter of law, one claim limitation may  
9 not be responsive to another merely because they are located in the same physical structure.” *Id.*  
10 at 1320 n.9. At least one court has expressly cited *IPD* for the proposition that “multiple claimed  
11 functions can share the same corresponding structure or structures.” *Morvil Tech. v. Medtronic*  
12 *Ablation Frontiers*, No. 10-CV-2088 BEN (BGS), 2012 U.S. Dist. LEXIS 113029, at \*51 (S.D.  
13 Cal. Aug. 10, 2012).

14 The instant case, of course, is somewhat different from *IPD*. In *IPD*, the Federal Circuit  
15 was confronted with *two* means-plus-function elements (the light beam demodulation means and  
16 the photo-sensitive detector means), and that is not the case here. But the underlying point of *IPD*  
17 still has application in the case at bar – *i.e.*, a valve is not automatically foreclosed from being  
18 structure for purposes of claim 1(b) just because it also shows up in claim 1(c).

19 Dr. Samuels protests, however, that just because a valve is part of the inflating process  
20 does not mean that the valve does the inflating itself; what does the actual inflating is the syringe  
21 and inflation tubing. Admittedly, Dr. Samuels has some support for his position from the ‘575  
22 specification, which states, *inter alia*, as follows: “Referring back to FIG. 1, cuff 17 is inflated by  
23 way of an inflation syringe 71 with an inflation material 73.” ‘575 patent, col. 4:33-34.

24 But, notably, other parts of the ‘575 specification indicate that a valve is not just a part of  
25 the inflation process; rather, it is a *necessary element* to accomplish the inflation. *Compare*  
26 *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1097 (Fed. Cir. 2008) (emphasis added) (noting  
27 that a “‘court may not import . . . structural limitations from the written description that are  
28 unnecessary to perform the claimed function’”) (emphasis added); *see also Wenger Mfg., Inc. v.*

1 *Coating Machinery Sys., Inc.*, 239 F.3d 1225, 1233 (Fed. Cir. 2001) (stating that “the court  
2 improperly restricted ‘air circulation means’ limitation to structure that was disclosed in the  
3 preferred embodiment, but was not necessary to perform the recited function of circulating air”).

- 4 • “The cuff **17** is inflated and deflated *by means of a valve*, indicated generally at **37** in  
5 FIGS. **4a** and **4b**, which is integral with inflation port **39** of cuff **17**.” ‘575 patent, col. 4:8-  
6 10 (emphasis added).
- 7 • “As shown in FIG. **4a**, when inflation tubing **61** is in an engaged configuration *with valve*  
8 **37**, mating end **63** separates opposing leaflets **51** and **53** so that cuff **17** may be inflated or  
9 deflated.” ‘575 patent, col. 4:17-20 (emphasis added).

10 That a valve is a necessary element to accomplish inflation is underscored by the fact that  
11 the inflation material can be “a saline-based fluid or a material that contains a photo-activated or  
12 heat-activated hardening agent or any hardening agent that hardens over time.” ‘575 patent, col.  
13 4:35-37. In either case, the valve is necessary to accomplish inflation (and not just prevent  
14 deflation after inflation is achieved, *see* Part II.D, *infra*) or the material will, in effect “leak out.”  
15 This is true even where the material contains a hardening agent because hardening is a process that  
16 takes at least some time.

17 In response, Dr. Samuels suggests that a valve is not necessary based on the language of  
18 claims 9 and 19. Claim 9 covers “[t]he inflatable intraluminal stent of claim **1** wherein the valve is  
19 of a breakaway design to permit separation *from the means for injecting*.” ‘575 patent, claim 9  
20 (emphasis added). Claim 19 covers “[t]he apparatus of claim **14** wherein the valve is of a  
21 breakaway design to permit separation *from the means for inflating*.” ‘575 patent, claim 19  
22 (emphasis added); *see also* ‘575 patent, claim 13 (addressing “[t]he inflatable intraluminal stent of  
23 claim **1** wherein the means for injecting an inflation material into said inflatable cuff to inflate it  
24 includes an inflation syringe and inflation tubing”). But TriVascular correctly notes that the  
25 Federal Circuit has “long held that a patentee cannot rely on claim differentiation to broaden a  
26 means-plus-function limitation beyond those structures specifically disclosed in the specification.”  
27 *Saffran v. Johnson & Johnson*, 712 F.3d 549, 563 (Fed. Cir. 2013); *see also Nomos Corp. v.*  
28 *BrainLAB USA, Inc.*, 357 F.3d 1364, 1368 (Fed. Cir. 2004) (noting that “our interpretation of the

corresponding structure comes from the written description, not from [a] dependent claim”; adding that “claim differentiation, which is a ‘guide, not a rigid rule,’ does not override the requirements of § 112, ¶ 6 when the ‘claim will bear only one interpretation’”; and thus concluding that the means for “generating at least one ultrasound image” includes both an ultrasound probe and a fixation device, not just the probe alone).

Accordingly, the corresponding structure for the two means-plus-function limitations identified above is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117), inflation tubing (61, 115), *and* a valve. Section 112 ¶ 6, of course, also provides coverage for equivalents thereof.

C. “inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff”

Dr. Samuels’s Proposed Construction	TriVascular’s Proposed Construction	Court’s Construction
A portion or portions of the outer surface of the cuff that protrude outward of the cuff upon inflation.	A portion or portions of the outer surface of the inflatable cuff that are themselves inflatable by being filled with fluid that protrude outward from the flat portions of the outer surface of the inflated cuff, including at least one ridge that goes around the cuff.	A portion or portions of the outer surface of the inflatable cuff that protrude outward of the cuff and that are themselves inflatable, <i>i.e.</i> , expandable by being filled with fluid, including at least one ridge that goes around the cuff.

The term can be found in, *e.g.*, claim 1(a).

As argued by TriVascular, the main dispute regarding the term seems to be whether the protrusions, which are themselves inflatable, must be inflatable by being filled with fluid. In his

1 reply brief, Dr. Samuels failed to address this point. *See* Reply at 6. That being the case, the  
2 Court adopts the limitation advocated for by TriVascular (*i.e.*, as unopposed).

3 Moreover, there is a substantive basis supporting the “fluid” limitation. Although the bulk  
4 of the ‘575 patent, including the specification, does not make any mention of the protrusions being  
5 filled with fluid, the specification does state: “As illustrated in FIG. 2, circumferential ridges 25  
6 are in fluid communication with the inflatable chamber 27 of cuff 17.” ‘575 patent, col. 3:54-56.  
7 *Cf. ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1374-75 (Fed. Cir. 2009) (agreeing with  
8 district court’s construction of “spike” to mean “‘an elongated structure having a pointed tip for  
9 piercing the seal, which tip may be sharp or slightly rounded’” because it is “appropriate ‘to rely  
10 heavily on the written description for guidance as to the meaning of the claims’” and “the  
11 specification ‘repeatedly and uniformly describes the spike as appointed instrument for the  
12 purpose of piercing a seal inside the valve’”).<sup>2</sup>

13 Furthermore, as TriVascular argues, the “fluid” limitation is supported based on what Dr.  
14 Samuels told the PTAB during the inter partes review (“IPR”) proceedings. In this regard,  
15 TriVascular makes a prosecution disclaimer-type argument. That doctrine “‘preclud[es] patentees  
16 from recapturing through claim interpretation specific meanings disclaimed during prosecution.’”  
17 *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1325 (Fed. Cir. 2015). While the doctrine does not apply

19 <sup>2</sup> Notably, the *ICU* court acknowledged that “we should not import limitations from the  
20 specification into the claims.” *ICU*, 558 F.3d at 1375. The court added, however, that

21 “the line between construing terms and importing limitations can be  
22 discerned with reasonable certainty and predictability if the court’s  
23 focus remains on understanding how a person of ordinary skill in the  
24 art would understand the claim terms.” Indeed, the court should  
25 focus on how such a person would understand the claim term “after  
26 reading the entire patent.” *The specification never suggests that the  
27 spike can be anything other than pointed.* As the district court  
28 noted, (1) each figure depicts the spike as elongated and pointed; (2)  
in each figure depicting an activated valve, the spike pierces the  
seal; and (3) the patents neither describe piercing as optional nor  
describe any non-piercing item as a spike. Moreover, *ICU* offers no  
support from any intrinsic or extrinsic source in support of its claim  
that the ordinary meaning of spike would include a non-pointed  
structure such as a tube or a straw.

*Id.* (emphasis added).

1 ““where the alleged disavowal of claim scope is ambiguous,”” it ““attaches and narrows the  
2 ordinary meaning of the claim congruent with the scope of the surrender”” where ““the patentee  
3 has unequivocally disavowed a certain meaning to obtain his patent.””<sup>3</sup> *Id.*

4 Before the PTAB, Dr. Samuels argued that the protrusions must be inflatable and that they  
5 “are unarguably identified by the circumferential ridges, such as ridges 25 in one embodiment  
6 clearly shown in Figure 2 . . . and are themselves in fluid communication with the inflatable  
7 chamber 27 of cuff 17.” Cohen Decl., Ex. 3 (Resp. at 5-6). He also argued that “the only  
8 supporting disclosure in the ‘575 patent is for a ridge which is itself part of the inflatable  
9 protrusion and contains fluid itself[;] [t]here simply is no support for the ridge being solid.”  
10 Cohen Decl., Ex. 3 (Resp. at 7). Ultimately, the PTAB adopted a construction in favor of Dr.  
11 Samuels, “determ[ing] that ‘inflatable protrusions’ are protrusions that are themselves inflatable,  
12 i.e., expandable by being filled with fluid,” as contended by Dr. Samuels. Cohen Decl., Ex. 4  
13 (PTAB Decision at 7, 10). Thus, based on the record, there is support for TriVascular’s argument  
14 that prosecution disclaimer is applicable here.

15 Accordingly, the Court construes the above-identified term as “a portion or portions of the  
16 outer surface of the inflatable cuff that protrude outward of the cuff and that are themselves  
17 inflatable, *i.e.*, expandable by being filled with fluid, including at least one ridge that goes around  
18 the cuff.”

19  
20 <sup>3</sup> At least two judges in this District have noted that prosecution disclaimer has viability in  
21 IPR proceedings, even though an IPR is technically an adjudicative proceeding rather than an  
22 examination. *See, e.g., Evolutionary Intelligence, LLC v. Sprint Nextel Corp.*, No. C013094513,  
23 2014 U.S. Dist. LEXIS 139066, at \*20 (N.D. Cal. Sept. 26, 2014) (Whyte, J.) (“The IPR  
24 proceedings will also add to the ‘536 Patent’s prosecution history. Prosecution history is an  
25 important part of the intrinsic record relevant to claim construction. Statements made by  
26 Evolutionary Intelligence during the IPR could disclaim claim scope, aid the court in  
27 understanding the meaning of the terms, or otherwise affect the interpretation of key terms.”);  
28 *Pragmatus AV, LLC v. Yahoo! Inc.*, No. C-13-1176 EMC, 2014 U.S. Dist. LEXIS 65813, at \*14-  
15 (N.D. Cal. May 13, 2014) (“Under Federal Circuit law, comments made by a patent holder  
during inter partes reexamination proceedings can limit claim scope. The same should be true  
now that inter partes review, rather than inter partes reexamination, is in effect.”). And even if  
prosecution disclaimer is not an exact fit because an IPR is an adjudicative proceeding, it is  
analogous to judicial estoppel. *See Abbott Labs. v. Church & Dwight Co.*, No. 07 C 3428, 2008  
U.S. Dist. LEXIS 103635, at \*25 (N.D. Ill. Dec. 22, 2008) (“not[ing] that the doctrine of  
prosecution disclaimer is arguably analogous to the concept of judicial estoppel, which applies  
only if the party to be estopped was successful in the prior proceeding”).

D. “a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation”

Dr. Samuels’s Proposed Construction	TriVascular’s Proposed Construction	Court’s Construction
<b>“a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation”</b>		
Any structure that affects fluid flow, formed or combined as a unit with the cuff, and is capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered the cuff to prevent deflation.	A device built-in to the [cuff, inflation port, or one of the cuffs] that has a movable part (such as leaflets) that open to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction does not cover inflation tubing inserted into an inflation port with an interference fit.	A valve, integral with the inflatable cuff, that has a movable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation.
<b>“a valve”</b>		
Any structure that affects fluid flow.	A device built-in to the [cuff, inflation port, or one of the cuffs] that has a movable part (such as leaflets) that open to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction	See above.

	does not cover inflation tubing inserted into an inflation port with an interference fit.	
<b>“for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation”</b>		
Capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered to cuff to prevent deflation.	A device built-in to the [cuff, inflation port, or one of the cuffs] that has a movable part (such as leaflets) that open to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction does not cover inflation tubing inserted into an inflation port with an interference fit.	See above.

The terms can be found in, *e.g.*, claim 1(c).

As a preliminary matter, the Court takes note that, according to TriVascular, the phrase “a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation” (*see, e.g.*, claim 1(c)) should be construed in its entirety. While Dr. Samuels has provided a construction for the entirety of the phrase, he also asserts that the Court should really just construe parts of that phrase separately, namely (1) “a valve” and (2) “for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.” *See* Op. Br. at 16 (arguing that “Trivascular has impermissibly combined several terms and characterized them as one term”). The Court agrees with TriVascular that it makes more sense to construe the phrase in its entirety rather than in isolated portions, especially given the particular disputes between the parties

1 regarding the terms in the context of the entire phrase.

2 In evaluating the phrase “a valve integral with the inflatable cuff for permitting entry of the  
3 inflation material from the means for injecting and thereafter sealing said cuff to prevent  
4 deflation,” the Court begins by noting that there is some ambiguity. More specifically, is the valve  
5 at issue one that (1) permits entry of the inflation material and that (2) *actually* seals the cuff  
6 itself?<sup>4</sup> Or is the valve at issue one that (1) permits entry of the inflation material and that (2)  
7 *permits* sealing of the cuff (but does not do the actual sealing itself)?<sup>5</sup> The grammatical structure  
8 of the claim language better supports the first interpretation – *i.e.*, the valve permits entry and  
9 actually seals the cuff itself. Notably, there is parallel construction between the words  
10 “permitting” and “sealing.” Compare ‘851 patent, claim 6(b)<sup>6</sup> (claiming “[a]n apparatus for  
11 affixing an endoluminal device to the walls of tubular structures with in the body comprising  
12 [*inter alia*] a valve integral with said cuff to permit inflation and deflation”). Moreover, at the  
13 claim construction hearing, Dr. Samuels never argued in favor of the second interpretation;  
14 instead, he agreed that claim 1(c) requires that the valve both permit entry and do the sealing itself.

15 With this understanding, the main question becomes whether a valve that permits entry and  
16 thereafter seals is a valve that (1) has moveable parts that open and close, such as a mitre valve  
17 (TriVascular’s position), or that (2) can be such a valve but that can also be a valve without  
18 movable parts, such as a breakaway valve (Dr. Samuels’s position). The Court concludes that Dr.  
19 Samuels’s position is not persuasive.

20 First, it is notable that the phrase states the valve permits entry and “*thereafter* seal[s] . . .  
21 to prevent deflation.” ‘575 patent, claim 1(c) (emphasis added). The use of the word “thereafter”  
22 is important. It indicates that, *after* inflation, the valve seals to prevent deflation. A breakaway  
23 valve may seal and prevent deflation *during* the inflation process (*i.e.*, while the inflation tubing is  
24

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25 <sup>4</sup> In other words, does the word “permitting” modify only the word “entry” and not the  
26 word “sealing”?

27 <sup>5</sup> In other words, does the word “permitting” modify both the word “entry” and the word  
28 “sealing”?

<sup>6</sup> The ‘851 patent is another patent owned by Dr. Samuels.

1 inserted), as Dr. Samuels argued at the hearing, but during and after are not the same thing. With  
2 a breakaway valve, after inflation, the inflation tubing is removed, *see* ‘575 patent, col. 4:24-27  
3 (stating that, “[r]eferring to FIG. 4b, once cuff 17 has been inflated (or deflated) to the desired  
4 level, a sharp tug on inflating tubing 61 in a direction away from inflation port 39 causes  
5 circumferential notch 65 [part of the inflation tubing] and circumferential rim 55 [part of the  
6 breakaway valve] to disengage”), and there is nothing in the ‘575 patent to indicate that the  
7 breakaway valve itself seals, as opposed to, *e.g.*, a hardening agent in the inflation material. *See*  
8 ‘575 patent, col. 4:34-43 (“The inflation material could be a saline-based fluid or a material that  
9 contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens  
10 over time. . . . After cuff 17 has been installed and inflated, the material 73 hardens over time to  
11 permanently affix stent 5 within the tubular structure of the body via circumferential ridges.”).

12 Second, although it is possible for the inflation material to seal itself allowing the  
13 breakaway valve to be removed, the ‘575 specification clearly contemplates that the inflation  
14 material can be a fluid *without* any hardening agent. *See* ‘575 patent, col. 4:34-37 (“The inflation  
15 material could be a *saline-based fluid* or a material that contains a photo-activated or heat-  
16 activated hardening agent or any hardening agent that hardens over time.”) (emphasis added).  
17 That being the case, claim 1 of the ‘575 patent requires a valve that permits entry and thereafter  
18 seals either with *or* without the use of any hardening agent in the inflation material. Indeed, this is  
19 underscored by dependent claim 7 which requires inflation material *with* a hardening agent. *See*  
20 ‘575 patent, claim 7 (covering “[t]he inflatable intraluminal stent of claim 1 wherein the inflation  
21 material includes a hardening agent”). Dr. Samuels has failed to explain how a breakaway valve  
22 could do the sealing (after inflation is completed) in a case where the fluid (inflation material)  
23 does not contain any hardening agent without, *e.g.*, a mitre valve. While, at the hearing, Dr.  
24 Samuels asserted that there could be some other kind of valve without movable parts that could do  
25 sealing, even without any hardening agent – *e.g.*, if the valve had a physical structure with a  
26 decreasing orifice size, such that, with the right pressure, inflation material could be forced in but  
27 would not thereafter “leak out” – he failed to offer any evidence showing that this was in fact  
28 possible. Furthermore, nothing in the patent specifications suggests such a valve. *See* note 2,

1 *supra*.

2 Third, as TriVascular points out, in multiple places in the specification, there are only  
3 references to a valve that seals being a valve that closes (such as a mitre valve) – which would  
4 require movable parts associated with the valve. *See, e.g.*, ‘575 patent, col. 4:29-32 (stating that,  
5 “[u]pon withdrawal of the mating end **63** of inflation tubing **61**, . . . opposing leaflets **51** and **53** of  
6 mitre valve **45** close to seal the inflated cuff **17**”); ‘575 patent, col. 6:26-29 (stating that, “[a]s the  
7 catheter is pulled away, the breakaway valve within port **123** releases inflation tubing **115** and the  
8 mitre valve [which has leaflets that open and close] seals port **123** in a manner similar to the one  
9 illustrated in FIG. **4b**”); *see also* note 2, *supra*. This is consistent with the position that Dr.  
10 Samuels took before the PTAB in the IPR proceeding. *See, e.g.*, Cohen Decl., Ex. 1 (Prelim.  
11 Resp. at 2) (stating that “[s]tent 5 also includes a means for injecting or inflating with an inflation  
12 material and a valve 45 [*i.e.*, a mitre valve<sup>7</sup>] for permitting entry of the inflation material into cuff  
13 17 and thereafter sealing cuff 17 to prevent deflation”); Cohen Decl., Ex. 3 (Resp. at 4) (stating  
14 that “[s]tent 5 also includes a valve 45 [*i.e.*, a mitre valve] for permitting entry of the inflation  
15 material into cuff 17, allowing deflation, and finally sealing cuff 17 to prevent deflation”).

16 Finally, dependent claims 8 and 9 are not sufficient to establish that a valve that seals after  
17 inflation can be one without movable parts. For example, claim 8 covers “[t]he inflatable  
18 intraluminal stent of claim **1** wherein the valve is a mitre valve.” ‘575 patent, claim 8. But simply  
19 because a mitre valve is called out in claim 8 does not thereby mean that a breakaway valve (or  
20 other valve without movable parts) is a valve that seals thereafter, as required in claim 1. A mitre  
21 valve is one specific kind of valve with movable parts; Dr. Samuels has not demonstrated that  
22 there are not others. *See also Phillips*, 415 F.3d at 1315 (noting that “the presence of a dependent  
23 claim that adds a particular limitation gives rise to a presumption that the limitation in question is  
24 not present in the independent claim”). Claim 9 covers “[t]he inflatable intraluminal stent of claim  
25 **1** wherein the valve is of a breakaway design to permit separation from the means for injecting.”  
26 ‘575 patent, claim 9. But claim 9 need not be interpreted to mean that a breakaway valve is

27  
28 <sup>7</sup> *See* ‘575 patent, col. 4:12-14 (stating that “[m]itre valve **45** features opposing leaflets **51**  
and **53** which are constructed of a non-elastomeric, biologically inert material”).

therefore a valve that seals after inflation, as required by claim 1. It does not preclude a breakaway valve in addition to, *e.g.*, a mitre valve as shown in the drawings. In other words, claim 9 can be interpreted to mean that the valve that actually seals in claim 1 (such as a mitre valve) is given an additional feature – *i.e.*, a breakaway design. In fact, that interpretation makes more sense given the language in claim 9 that the breakaway design’s purpose is “to permit separation from the means for injecting,” and therefore not to seal.

Accordingly, the Court construes the phrase “a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation” as follows: “a valve, integral with the inflatable cuff, that has a movable part or parts (such as leaflets) that open to permit entry of the inflation material and thereafter close to seal the cuff to prevent deflation.” The Court need not add limitations beyond that, as suggested by TriVascular, as a valve involving inflation tubing inserted into an inflation port with an interference fit does not have a movable part or parts. Likewise, the Court need not add language regarding capability, as proposed by Dr. Samuels, because it is confusing and unnecessary given the construction above.

E. “inflatable and deflatable cuff of generally hollow cylindrical continuation [sic configuration]”<sup>8</sup>

Dr. Samuels’s Proposed Construction	TriVascular’s Proposed Construction	Court’s Construction
Cuff of generally hollow configuration.	A band-like structure that has an inner surface and outer surface creating an inflatable chamber that may be inflated by filling the chamber with fluid or deflated by allowing	A cuff, of generally hollow configuration, that has an inner surface and an outer surface and an inflatable and deflatable chamber in between the surfaces.

<sup>8</sup> The Court **GRANTS** TriVascular’s administrative motion to file notice of supplemental citation. *See* Docket No. 90.

	the fluid to leave in ordinary use.	
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This term can be found in, *e.g.*, claim 1(a).

As a preliminary matter, the Court takes note that Dr. Samuels has asked for construction of a slightly narrower term – *i.e.*, “cuff of generally hollow cylindrical continuation [sic configuration].” However, it is proper to construe the broader term, as advocated by TriVascular, particularly given Dr. Samuel’s objection to TriVascular’s proffered construction. *See, e.g.*, Reply at 12 (arguing that “[t]here is no support for adding the additional language of an inflatable chamber, nor is it needed”).

The crux of the dispute here (which was not fully fleshed out until the hearing) is whether a cuff has an inflatable chamber between the cuff’s inner surface and outer surface. *See, e.g.*, ‘575 patent, Fig. 2 (inflatable chamber at **27**); ‘575 patent, col. 3:54-56 (“As illustrated in FIG. **2**, circumferential ridges **25** are in fluid communication with the inflatable chamber **27** of cuff **17**.”). TriVascular argues that a cuff does; Dr. Samuels argues that a cuff can have an inflatable chamber but such is not required; that is, it is permissible to have only the inflatable protrusion(s) inflated.

Dr. Samuels’s position is without merit. The cuff is expressly described as “inflatable and deflatable” in the term. To be inflatable, there must be a chamber within the cuff that can be filled with inflation material. If the ‘575 patent was intended to cover only an expandable cuff, then Dr. Samuels could easily have used the term “expandable” or a word akin thereto. Instead, he chose the word “inflatable,” a word that is also used in the patent term “inflatable protrusions.” Dr. Samuels has failed to explain why “inflatable” should have one meaning when used in conjunction with the cuff and a different meaning when used in conjunction with the protrusions.<sup>9</sup>

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<sup>9</sup> In a supplemental brief, Dr. Samuels argued that “inflatable cuff” may still refer to a cuff with only the inflatable protrusion(s) inflated because the inflatable protrusion(s) is/are *part* of the cuff. *See* Docket No. 91 (Dr. Samuels’s Supp. Br. at 2) (arguing that “the inflatable cuff of claim 1 may be inflated by inflation of just the inflatable protrusion(s) which is/are part of the ‘cuff’ as claimed”). But this argument is not persuasive because the cuff is the entire structure; thus, an “inflatable cuff” must mean that the entire structure is inflated. Notably, nowhere in the specification is it suggested that an inflatable cuff can be a cuff with only a portion of it inflated. *See* note 2, *supra*. Moreover, given that the claim allows for only one circumferential ridge, Dr.

At the hearing, Dr. Samuels pointed to independent claims 14 and 23 as supportive of his position, *see generally Tandon Corp. v. U.S. Int’l Trade Comm’n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987) (stating that “[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims” and that, “[t]o the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant”), but the Court is unpersuaded. Admittedly, claim 14 does refer to “a cuff having a collapsible lumen, an inner surface and a friction-enhancing outer surface with an inflatable and deflatable chamber disposed there between.” ‘575 patent, claim 14. But simply because the cuff, as described in claim 14, refers to an inflatable and deflatable chamber, does not mean that the cuff, as described in other claims (*e.g.*, claim 1) does not have such a chamber. “The doctrine of claim differentiation is at its strongest . . . ‘where the limitation that is sought be “read into” an independent claim already appears in a dependent claim.’” *InterDigital Communs., LLC v. ITC*, 690 F.3d 1318, 1324 (Fed. Cir. 2012). But here, claims 14 and 23 are not dependent claims; they, like claim 1, are independent claims. Notably, the Federal Circuit has stated that it has

been cautious in assessing the force of claim differentiation in particular settings, recognizing that patentees often use different language to capture the same invention, discounting it where it is invoked based on independent claims rather than the relation of an independent and dependent claim, and not permitting it to override the strong evidence of meaning supplied by the specification.

*Atlas IP, LLC v. Medtronic, Inc.*, No. 2015-1071, 2015 U.S. App. LEXIS 18819, at \*16 (Fed. Cir. Oct. 29, 2015). The Court also notes that “[a] further reason for not applying the doctrine of claim differentiation in this case is that the [claims at issue] are not otherwise identical.” *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) (noting that “there are numerous other differences varying the scope of the claimed subject matter”). Claim 1, for example, is targeted to an “inflatable intraluminal stent” specifically whereas claim 14 is directed more broadly to an “apparatus for disposition within the lumen of a tubular structure.”

Samuels’s construction makes little sense because, if only that ridge (and not the cuff) is inflated, the cuff would consist of simple ring and not a cylinder.

Accordingly, the Court construes the phrase “inflatable and deflatable cuff of generally hollow cylindrical continuation [sic configuration]” as “a cuff, of generally hollow configuration, that has an inner surface and an outer surface and an inflatable and deflatable chamber in between the surfaces.” The Court declines to provide a specific definition for the term “cuff” (*e.g.*, as a band-like structure) as the term is understandable to a lay person.

F. “affixing the cuff with [sic within] the lumen of the tubular structure without penetration of the tubular structure”

Dr. Samuels’s Proposed Construction	TriVascular’s Proposed Construction	Court’s Construction
Causing the cuff to resist movement within the lumen of the tubular structure without penetration of the tubular structure.	The cuff is fixedly secured to the interior of the tubular structure to hold it in place without penetration of the tubular structure.	Plain and ordinary meaning.

This term can be found in, *e.g.*, claim 14(b).

The Court sees no need to define the claim term, not only because the word “affixing” is not a term beyond a lay person’s comprehension but also because there is no real difference between the parties’ proposed constructions. This is substantiated by the specification of the patent which describes “affixing” in the following contexts:

- “If the initial placement of the stent within the tubular structure is not optimal, it may be deflated, repositioned to the optimal position and reinflated so as to again be affixed to the tubular walls via its outer surface.” ‘575 patent, col. 2:39-42.
- “As shown in FIG. 1, outer surface 23 features a number of inflatable ridges 25 disposed about its circumference. While inflatable ridges are shown in the FIGS., any friction-enhancing outer surface, that would secure the inflated stent to the interior wall of a tubular structure without penetrating it, could be used.” ‘575 patent, col. 3:33-37.

- 1 • “As illustrated in FIG. 3, the outer surface **30** of the cuff is made coarse by a combination  
2 of raised portions **31** and lowered portions **33**. These surface features allow the inflated  
3 stent to grip the interior walls of a tubular structure with a force that is sufficient to prevent  
4 its migration.” ‘575 patent, col. 3:62-66.
- 5 • “In addition, it may be desirable in some applications to provide the cuff with an outer  
6 surface that promotes tissue ingrowth. This would allow the stent to become more  
7 integrated, and thus more firmly affixed, within the tubular structure as time progresses.”  
8 ‘575 patent, col. 4:1-5.
- 9 • “As shown in FIGS. 5c and 6c, stent **89** is inflated so that the size of the lumen of stent **89**  
10 approximates the lumen size of the original, unconstructed blood vessel. By doing so,  
11 constricted portion **83** is compressed between blood vessel wall **85** and stent **89**, the latter  
12 of which is fixed in place by way of protruding ridges **91**.” ‘575 patent, col. 4:59-64.
- 13 • “A unique feature of the present invention is its capability of being optimally positioned  
14 within a tubular structure in the body (in this case, a blood vessel) without causing damage  
15 to the surrounding tissue. Specifically, after stent **89** has been inflated so that ridges **91**  
16 affix the stent to the tubular walls without penetration, the position of the stent is examined  
17 fluoroscopically to determine if it is optimal. If not, stent **89** may be deflated, repositioned  
18 and then reinflated.” ‘575 patent, col. 4:66-5:7.
- 19 • “The stent-graft is secured to the vessel walls via ridges **96** so that blood passes through  
20 graft **92**.” ‘575 patent, col. 5:32-33.

21 Dr. Samuels’s position, as articulated during the IPR proceedings, does not indicate  
22 anything different. *See* Cohen Decl., Ex. 11 (Clark Decl. ¶¶ 5(a), 8) (referring to the ridges  
23 “holding the stent in place” and “maintain[ing] a desired position”); Cohen Decl., Ex. 12 (Samuels  
24 Decl. ¶ 4(b)) (noting that the stent can be “held fixed in a desired location”).

25 Moreover, claim 14(b) itself reads in full as follows: “said friction-enhancing outer surface  
26 featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the  
27 inflatable cuff and affixing the cuff with the lumen of the tubular structure without penetration of  
28 the tubular structure when the cuff is fully inflated *so that movement of the cuff in a longitudinal*

1 *direction with respect to the tubular structure is prevented.*” ‘575 patent, claim 14(b) (emphasis  
2 added). The meaning of “affix” is clear, particularly when viewed in the context of the italicized  
3 language. Given the context of the full claim limitation, there is no need to reiterate the point that  
4 movement is resisted or that the cuff is held in place.

5 G. “said friction-enhancing outer surface engaging the interior of the tubular structure without  
6 penetration to prevent the cuff from moving”

8 Dr. Samuels’s Proposed	TriVascular’s Proposed	Court’s Construction
9 Construction	Construction	
10 Outer surface capable of	Said friction enhancing outer	Plain and ordinary meaning.
11 engaging the interior of the	surface gripping the interior of	
12 tubular structure without	the tubular structure with	
13 penetration and capable of	sufficient force to fixedly	
14 preventing the cuff from	secure the cuff to keep/hold it	
15 moving and enhancing	in place without penetration of	
16 friction.	the tubular structure.	

17 This term can be found in, *e.g.*, claim 1(a).


18 Basically, the dispute here is similar to the one immediately above, and the Court therefore  
19 rests on plain and ordinary meaning.

20 **III. CONCLUSION**

21 For the foregoing reasons, the Court adopts the above constructions for the claim terms at  
22 issue.

23 **IT IS SO ORDERED.**

24  
25 Dated: November 12, 2015

26   
27 EDWARD M. CHEN  
28 United States District Judge

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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION**

DR. SHAUN L. W. SAMUELS,  
  
Plaintiff,  
  
vs.  
  
TRIVASCULAR, INC., ET AL.  
  
Defendants.

CASE NO. 3:13-CV-02261-EMC

**STIPULATION AND  
[PROPOSED] ORDER AND  
FINAL JUDGMENT OF NON-  
INFRINGEMENT OF THE '575  
PATENT**

TRIVASCULAR, INC.,  
  
Counter-Claimant,  
  
vs.  
  
DR. SHAUN L. W. SAMUELS,  
  
Counter-Defendant.

Judge: Hon. Edward M. Chen

WHEREAS, Plaintiff Dr. Shaun L.W. Samuels ("Samuels") and Defendant TriVascular, Inc. ("TriVascular"), and individual Defendants Michael A. Chobotov, Robert G. Whirley, and Joseph W. Humphrey ("Individual Defendants") ("the Parties") stipulate and move for entry of judgment of non-infringement under all claims of U.S. Patent No. 6,007,575 ("the '575 patent") as to the Defendants based on the Court's Claim Construction Order (Dkt. No. 92);

1 WHEREAS, entering judgment of non-infringement now will allow the parties to forego  
2 further litigation in this Court of the '575 patent, while preserving Samuels's right to appeal the  
3 Court's Claim Construction Order (Dkt. No. 92);

4 WHEREAS, Civil L.R. 54-1(a) requires that Bill of Costs be served and filed no later than 14  
5 days after entry of judgment;

7 WHEREAS, Civil L.R. 54-5 requires that a Motion for Fees be served and filed no later than  
8 14 days after entry of judgment; and

9 WHEREAS, Samuels intends to appeal the Court's forthcoming entry of a judgment of non-  
10 infringement based on this stipulation.

11 IT IS HEREBY STIPULATED AND AGREED by the Parties, subject to the approval of the  
12 Court, as follows:

13 1. This is a patent infringement action brought by Samuels against TriVascular, Michael  
14 A. Chobotov, Robert G. Whirley, and Joseph W. Humphrey. Samuels filed this patent litigation  
15 action against TriVascular on May 17, 2013. *See* Dkt. No. 1. Samuels filed a Second Amended  
16 Complaint on August 13, 2015 adding the Individual Defendants. *See* Dkt. No. 77. The Defendant  
17 TriVascular filed an Answer, Affirmative Defenses and Counterclaims to Plaintiff's Second  
18 Amended Complaint on August 27, 2015 (Dkt. No. 78), and the Individual Defendants filed their  
19 Answer and Affirmative Defenses on August 27, 2015 (Dkt. No. 79). TriVascular's pending  
20 counterclaims are patent counterclaims of non-infringement (First Counterclaim) and invalidity  
21 (Second Counterclaim), as well as counterclaims for breach of contract and promissory estoppel  
22 (Third, Fourth and Fifth Counterclaims). Plaintiff has asserted infringement of claims 1-7, 9-11, 13-  
23 17, 19-21, and 23-24 of the '575.

24 2. On November 12, 2015, this Court construed certain claim terms found in the '575  
25 patent. (Claim Construction Order, Dkt. No. 92).

3. The Parties disputed the construction of the term “means for injecting an inflation material into said cuff to inflate it “ and “means for inflating the cuff with inflation material” of claims 1, 14 and 23 of the ’575 patent as follows:

Claim Term	Samuels	Defendants
<b>means for injecting an inflation material into said cuff to inflate it [claim1]</b>	<p>This is a means-plus-function element governed by 35 U.S.C. §112, ¶ 6.</p> <p><b>Function:</b> The function is injecting an inflation material into said cuff to inflate it.</p> <p><b>Structure:</b> The corresponding structure is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71, 117) and inflation tubing (61, 115).</p>	<p>This is a means-plus-function limitation governed by 35 U.S.C. §112, ¶ 6.</p> <p><b>Function:</b> The function is injecting an inflation material into said cuff to inflate it.</p> <p><b>Structure:</b> The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117) containing an inflation material; inflation tubing (61, 115) with a mating end (63) that opens a valve by separating opposing leaflets (51, 53) that are in an inflation port (39, 123) to inflate the cuff.</p>

Claim Term	Samuels	Defendants
<b>means for inflating the cuff with inflation material [claim 14]</b>	<p>This is a means-plus-function element governed by 35 U.S.C. §112, ¶ 6.</p> <p><b>Function:</b> The function is inflating the cuff/plurality of cuffs with inflation material.</p> <p><b>Structure:</b> The corresponding structure is an inflation device, such as the kind of syringe shown in Figs. 1 and 9a-9c (71, 117) and inflation tubing</p>	<p>This is a means-plus-function limitation governed by 35 U.S.C. §112, ¶ 6.</p> <p><b>Function:</b> The function is inflating the cuff/plurality of cuffs with inflation material.</p> <p><b>Structure:</b> The corresponding structure is an inflation syringe of the kind shown in Figs. 1 and 9a-9c (71, 117) containing</p>
<b>means for inflating the plurality of cuffs with inflation material [claim 23]</b>		

	(61, 115)	an inflation material; inflation tubing (61, 115) with a mating end (63) that opens a valve by separating opposing leaflets (51, 53) that are in an inflation port (39, 123) to inflate the cuff with the inflation material.
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4. The Parties also disputed the construction of the term “valve” of claims 1, 14 and 23 of the ’575 patent as follows:

Claim Term	Samuels	Defendants
<b>a valve integral [with the inflatable cuff, cl. 1] [with said inflation port, cl. 14] [with one of the plurality of cuffs, cl. 23] for permitting entry of the inflation material . . . and thereafter sealing said cuff to prevent deflation</b>	Any structure that affects fluid flow, formed or combined as a unit with the cuff, and is capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered the cuff to prevent deflation.	a device built-in to the [cuff] [inflation port] [one of the cuffs] that has a movable part (such as leaflets) that opens to permit entry of the inflation material and thereafter closes to seal the cuff to prevent deflation. This construction does not cover inflation tubing inserted into an inflation port with an interference fit.
<b>Claim Term</b>	<b>Samuels</b>	<b>Defendants</b>
<b>a valve</b>	Any structure that affects fluid flow	See above
<b>Claim Term</b>	<b>Samuels</b>	<b>Defendants</b>
<b>“for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation”</b>	Capable of not stopping inflation material from entering the cuff from the means for injecting and capable of stopping inflation material from leaving the cuff after the injection material has entered to cuff to prevent deflation.	See above

5. The Parties also disputed the construction of the term “inflatable and deflatable cuff,” “a cuff,” and “a plurality of cuffs” of claims 1, 14 and 23 of the ‘575 patent as follows:

Claim Term	Samuels	Defendants
<b>inflatable and deflatable cuff of generally hollow cylindrical continuation (sic. configuration)</b>	Cuff of generally hollow cylindrical configuration (per Claim Construction Order)	a band-like structure that has an inner surface and outer surface creating an inflatable chamber that may be inflated by filling the chamber with fluid or deflated by allowing the fluid to leave in ordinary use

6. The Parties now stipulate that, given the Court’s construction of the term “means for injecting an inflation material into said cuff to inflate it” as set forth in the Court’s Claim Construction Order (Dkt. No. 92) as well as the statement at page 7 of the cuff 17 having to be “inflated and deflated by means of a valve, indicated generally at 37 in FIGS 4a and 4b, which is integral with inflation port 39 of cuff 17” in the ‘575 Patent, Samuels cannot prove infringement of claims 1-7, 9-11, and 13 of the ‘575 patent by the Defendants.

7. The Parties now stipulate that, given the Court’s construction of the term “means for inflating the cuff with inflation material” as set forth in the Court’s Claim Construction Order (Dkt. No. 92) as well as the statement at page 7 of the cuff 17 having to be “inflated and deflated by means of a valve, indicated generally at 37 in FIGS 4a and 4b, which is integral with inflation port 39 of cuff 17” in the ‘575 Patent Samuels cannot prove infringement of claims 14-17, 19-21, and 23-24 of the ‘575 patent by the Defendants.

8. The Parties further stipulate that, given the Court’s construction of the term “a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation” as set forth in the Court’s Claim Construction Order (Dkt. No. 92), Samuels cannot prove infringement of claims 1-7, 9-11 and 13 of

1 the '575 patent by the Defendants.

2 9. The Parties further stipulate that, given the Court's construction of the term "a valve  
3 integral with the inflatable cuff for permitting entry of the inflation material from the means for  
4 inflating and thereafter sealing said cuff to prevent deflation" as set forth in the Court's Claim  
5 Construction Order (Dkt. No. 92), Samuels cannot prove infringement of claims 14-17, 19-21, and  
6 23-24 of the '575 patent by the Defendants.  
7

8 10 The Parties further stipulate that, given the Court's construction of the term "a valve"  
9 as set forth in the Court's Claim Construction Order (Dkt. No. 92), Samuels cannot prove  
10 infringement of claims 1-7, 9-11, 13-17, 19-21, and 23-24 of the '575 patent by the Defendants.  
11

12 11. The Parties further stipulate that, given the Court's construction of the term "for  
13 permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff  
14 to prevent deflation" as set forth in the Court's Claim Construction Order (Dkt. No. 92), Samuels  
15 cannot prove infringement of claims 1-7, 9-11 and 13 of the '575 patent by the Defendants.

16 12. The Parties further stipulate that, given the Court's construction of the term "for  
17 permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff  
18 to prevent deflation" as set forth in the Court's Claim Construction Order (Dkt. No. 92), Samuels  
19 cannot prove infringement of claims 14-17, 19-21, and 23-24 of the '575 patent by the Defendants.  
20

21 13. The Parties further stipulate that, given the Court's construction of the term  
22 "inflatable and deflatable cuff of generally hollow cylindrical continuation [sic configuration]" as set  
23 forth in the Court's Claim Construction Order (Dkt. No. 92), including that "an 'inflatable cuff' must  
24 mean that the entire structure is inflated" as set forth in footnote 9 of Dkt. No. 92, Samuels cannot  
25 prove infringement of claims 1-7, 9-11, and 13 of the '575 patent by the Defendants.

26 14. The Parties further stipulate that the Court enter judgment of non-infringement as to  
27 the '575 patent to conserve judicial resources and to avoid the time and expense of further discovery  
28

1 and motion practice related to the '575 patent. Plaintiff is not asserting any other claims of the '575  
2 patent other than claims 1-7, 9-11, 13-17, 19-21, and 23-24. Upon entry of such judgment, Samuels  
3 intends to appeal the Court's forthcoming entry of judgment of non-infringement based on this  
4 stipulation.

5  
6 15. The Parties further stipulate that Rule 54(b) authorizes a district court to "direct entry  
7 of a final judgment as to one or more, but fewer than all, claims ... if the court expressly determines  
8 that there is no just reason for delay." Fed. R. Civ. P. 54(b). In view of the Court's claim  
9 construction, as described above, and because the non-infringement issue is separable from the  
10 remaining counterclaims, in the interest of sound judicial administration, there is no just reason for  
11 delaying the entry of final judgment of non-infringement as to the '575 patent, and final judgment of  
12 non-infringement, subject to the Court's approval, is hereby entered pursuant to Fed. R. Civ. P.  
13 54(b).

14  
15 16. As to TriVascular's Second through Fifth Counterclaims, the Parties further stipulate  
16 that the counterclaims, subject to the Court's approval, are hereby stayed pending Samuels's appeal  
17 of the judgment of non-infringement as to the '575 patent. Defendants are preserving their rights  
18 and by entering into this stipulation Defendants do not waive the right to assert non-infringement  
19 under any claim limitations or claim constructions if the case is remanded. The stay shall be lifted  
20 after the appellate court's issuance of the mandate regarding Samuels's appeal of the Court's  
21 judgment, or if Samuels later chooses to abandon an appeal, the stay shall be lifted after Samuels  
22 provides notice that he is abandoning the appeal.

23  
24 17. The Parties further stipulate that in order to promote judicial efficiency and to  
25 conserve litigation costs, the deadlines for the Bill of Costs and Motion for Fees (including Motion  
26 for Fees pursuant to 35 U.S.C. § 285) concerning the non-infringement judgment that is the subject  
27 of this Stipulation be delayed until 21 days after the appellate court's issuance of the mandate  
28

1 regarding Samuels's appeal of the Court's judgment, or if Samuels later chooses to abandon an  
2 appeal, the deadlines be delayed until 21 days after Samuels provides notice that he is abandoning  
3 the appeal.

4 **IT IS SO AGREED AND STIPULATED:**

5  
6 DATED: December 15, 2015

7 Respectfully submitted,

8 /s/ Marc H. Cohen

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23 **ATTESTATION OF CONCURRENCE IN FILING**

24 I, James D. Petruzzi, am the ECF User whose identification and password are being used to  
25 file this Joint Stipulation. In compliance with Local Rule 5-1(i)(3), I hereby attest that Marc H.  
26 Cohen of Kirkland & Ellis, LLP has concurred in this filing.

27 /s/ James D. Petruzzi

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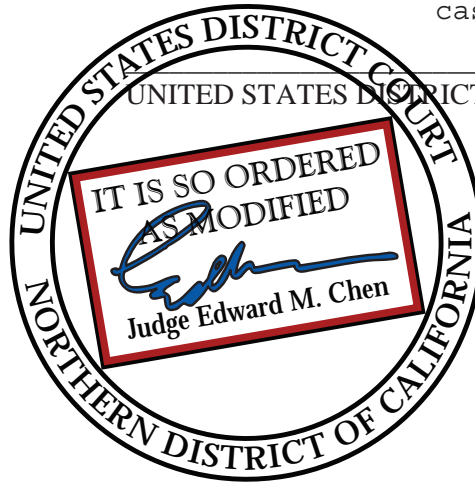
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jdpetruzzi@gmail.com

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**PURSUANT TO STIPULATION, IT IS SO ORDERED.** The Clerk of the Court  
is directed to close this  
case.

DATED: 12/17/15

UNITED STATES DISTRICT COURT JUDGE



**CERTIFICATE OF SERVICE**

I hereby certify that on December 15, 2015 that a copy of the foregoing document is being electronically filed with the Clerk of the United States District Court for the Northern District of California by using the CM/ECF system, which will send notice of such filing to all counsel of record.

Dated: December 15, 2015

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US006007575A

**United States Patent** [19]  
**Samuels**

[11] **Patent Number:** **6,007,575**  
 [45] **Date of Patent:** **Dec. 28, 1999**

[54] **INFLATABLE INTRALUMINAL STENT AND METHOD FOR AFFIXING SAME WITHIN THE HUMAN BODY**

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 94025

[21] Appl. No.: **08/870,745**

[22] Filed: **Jun. 6, 1997**

[51] **Int. Cl.**<sup>6</sup> ..... **A61F 2/02**; A61F 2/04;  
 A61F 2/06; A61M 39/00

[52] **U.S. Cl.** ..... **623/1**; 623/11; 623/12;  
 606/192; 606/194; 606/195; 606/198

[58] **Field of Search** ..... 623/1, 12, 11;  
 606/192, 194, 195, 198

[56] **References Cited**

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*Primary Examiner*—Paul B. Prebilic

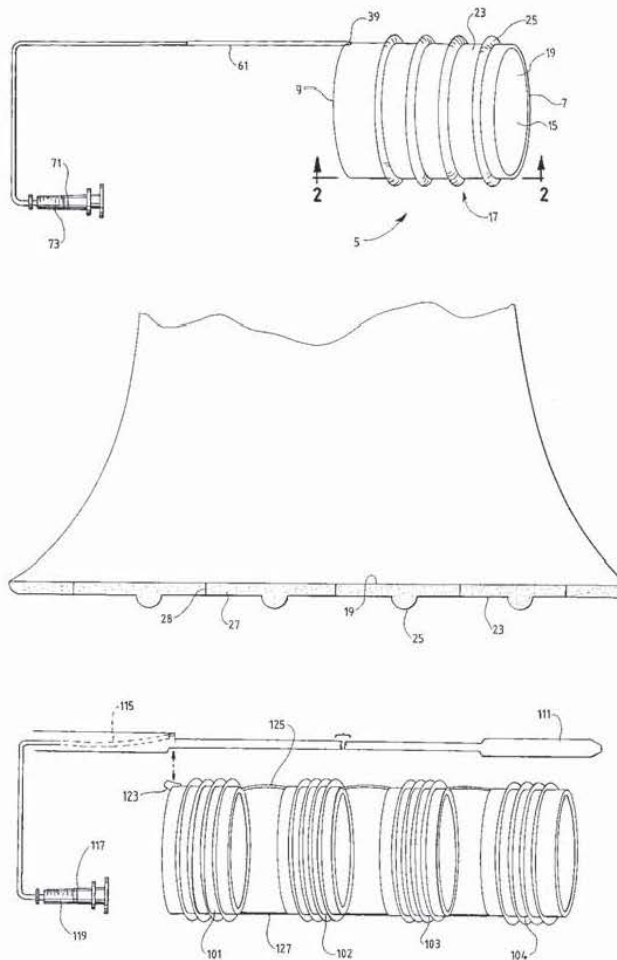
*Assistant Examiner*—Choon P. Koh

*Attorney, Agent, or Firm*—Rudnick & Wolfe

[57] **ABSTRACT**

An inflatable intraluminal stent for attachment to the interior surface of a tubular structure within the human body is disclosed. The stent features a cuff having an inflatable chamber and a friction-enhancing outer surface. The friction-enhancing outer surface engages the interior surface of the tubular structure without penetration when the inflatable cuff is in an inflated condition. An intraluminal medical device may be attached to the inner surface of the stent. A valve is integral with the inflatable cuff and allows for the inflation, deflation and sealing of the inflatable cuff.

**24 Claims, 10 Drawing Sheets**



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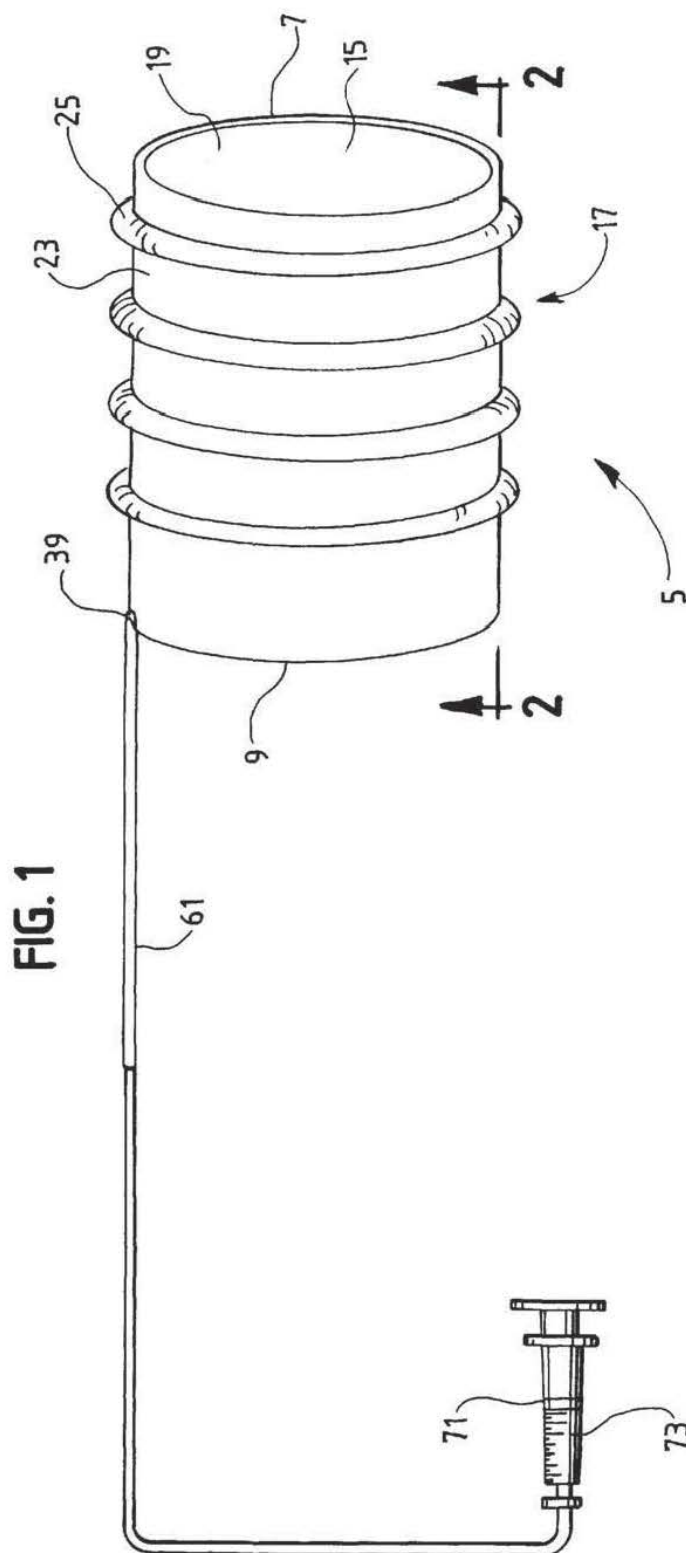
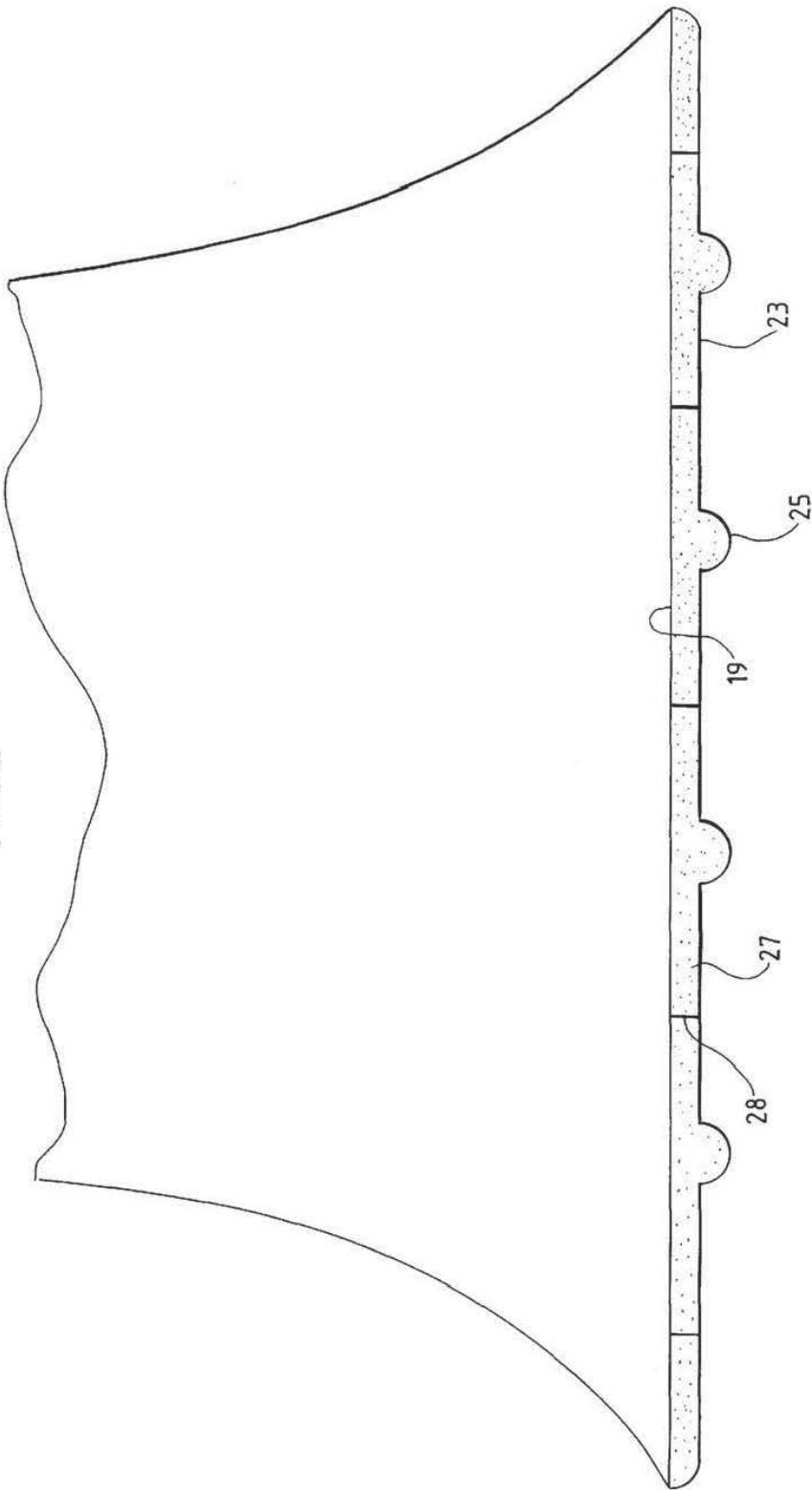


FIG. 2

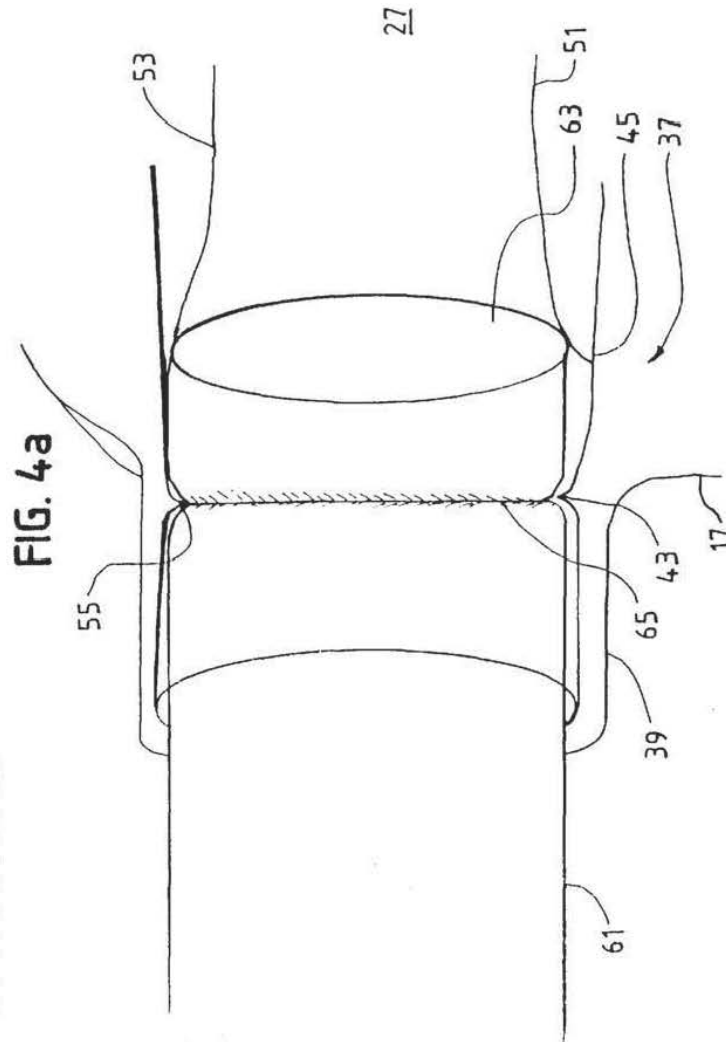
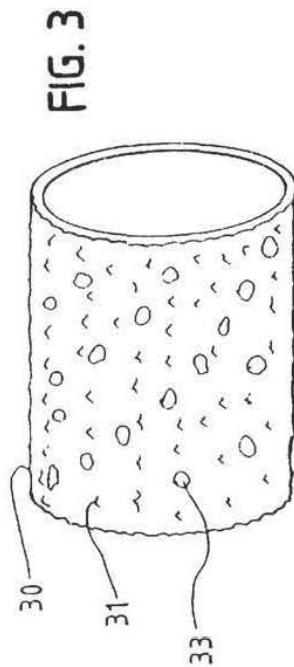


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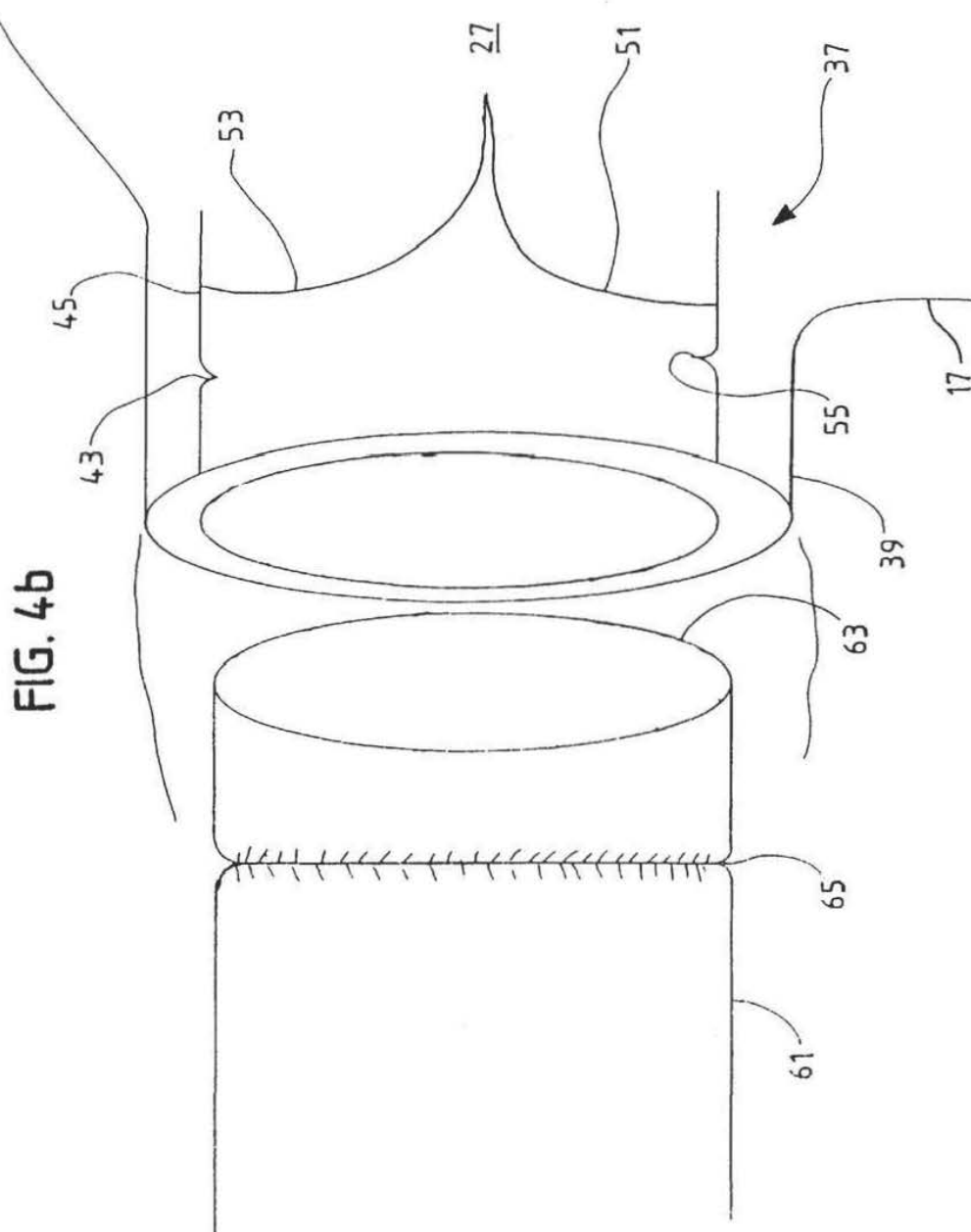


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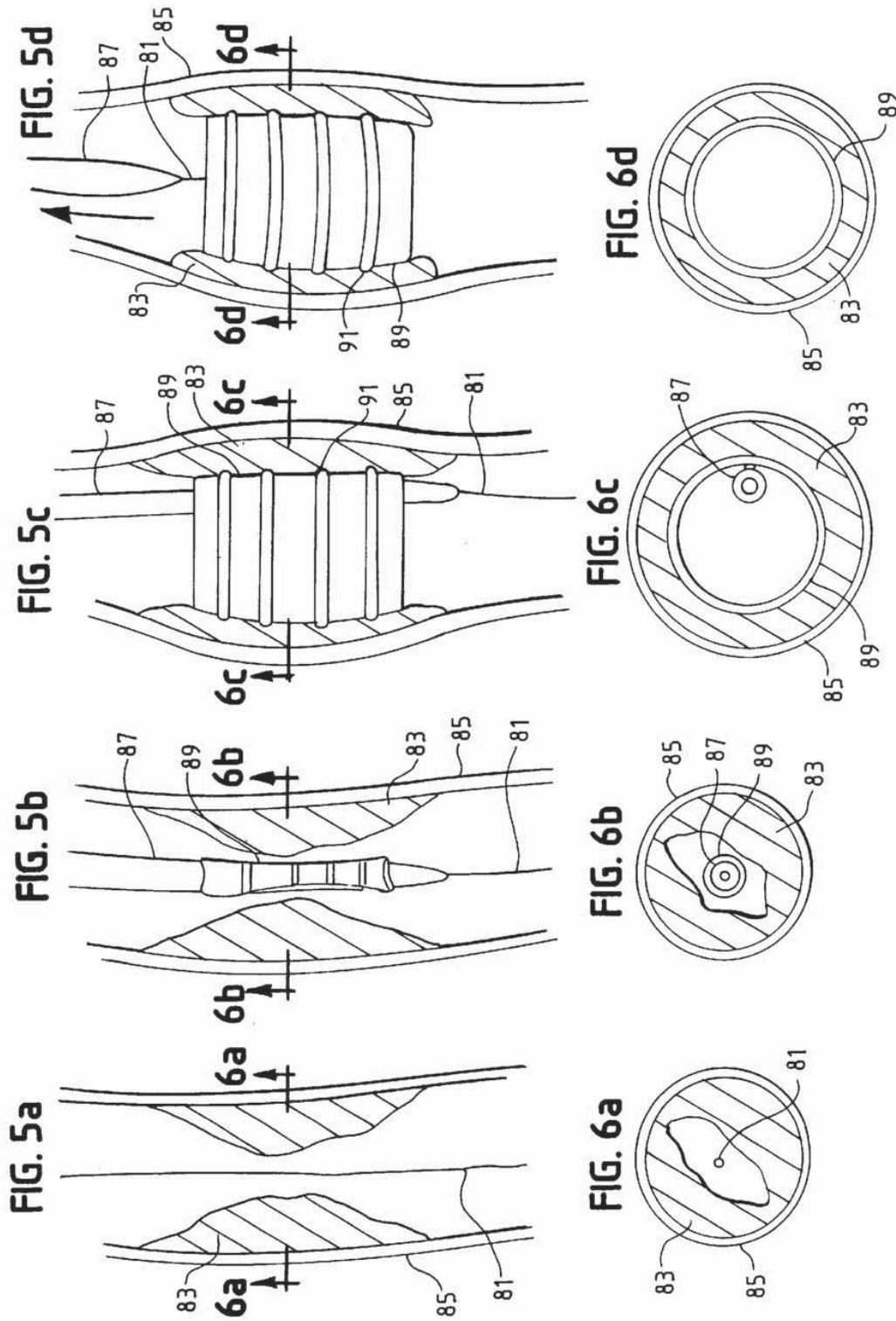
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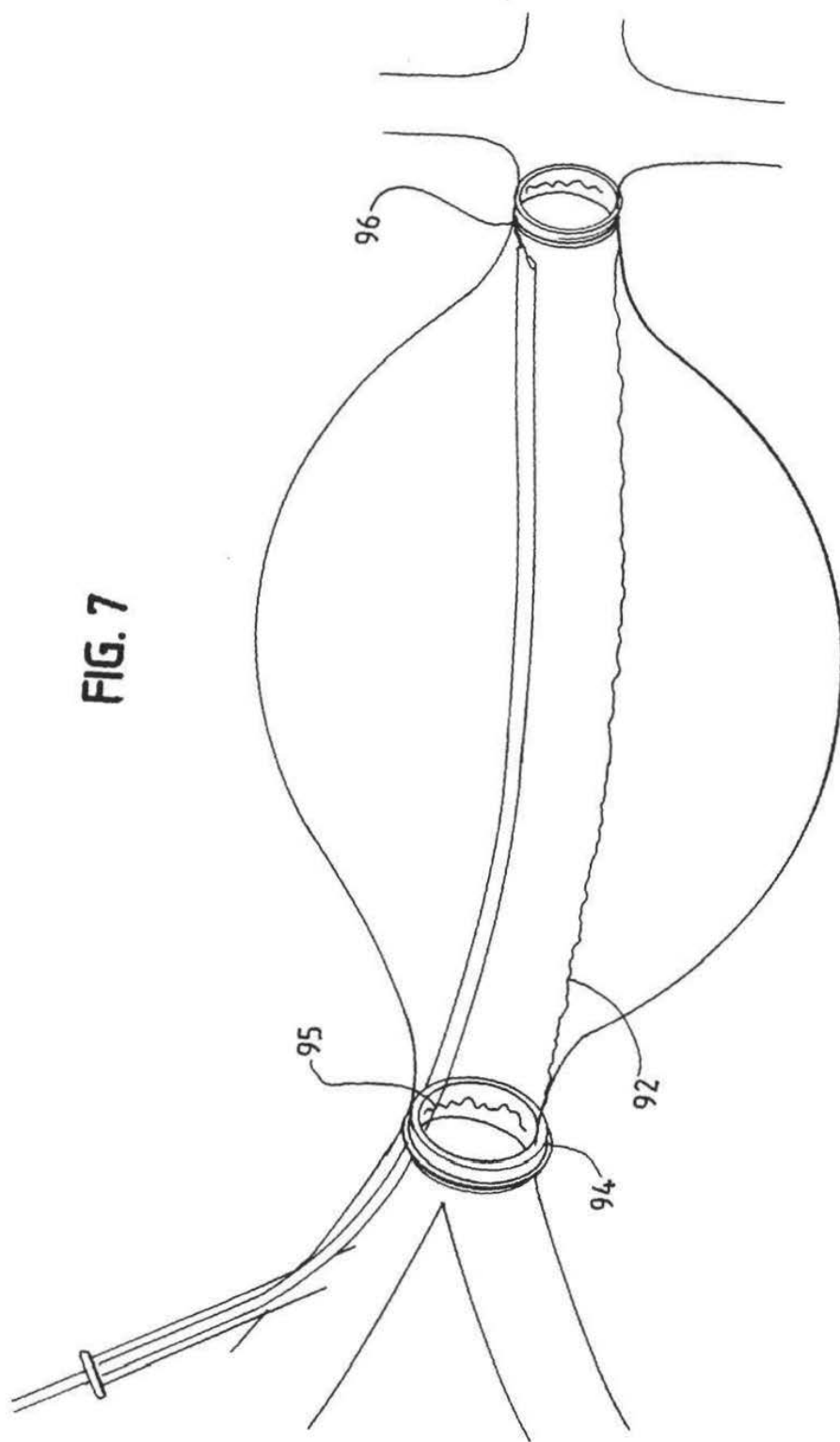
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FIG. 7



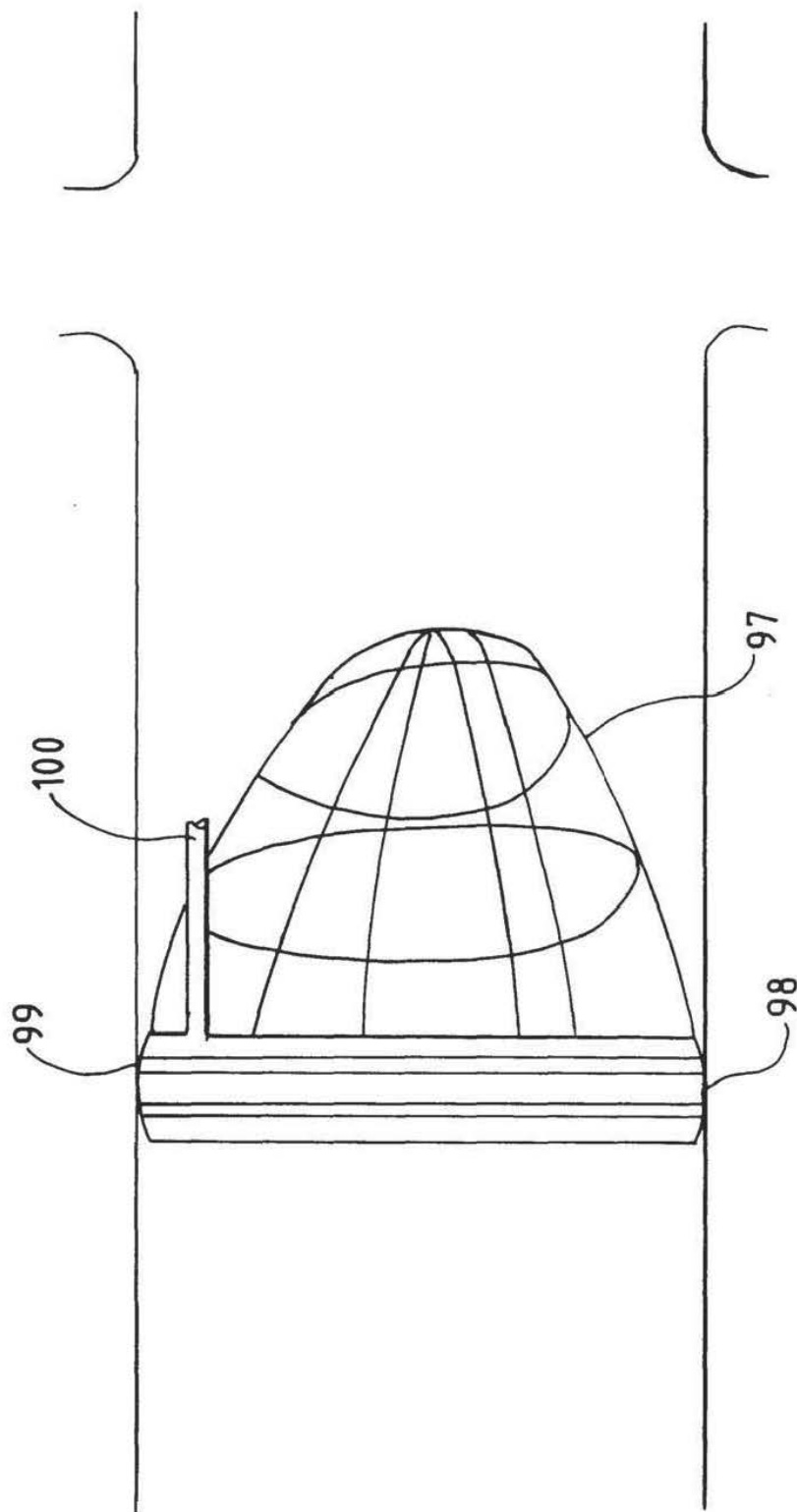
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FIG. 8



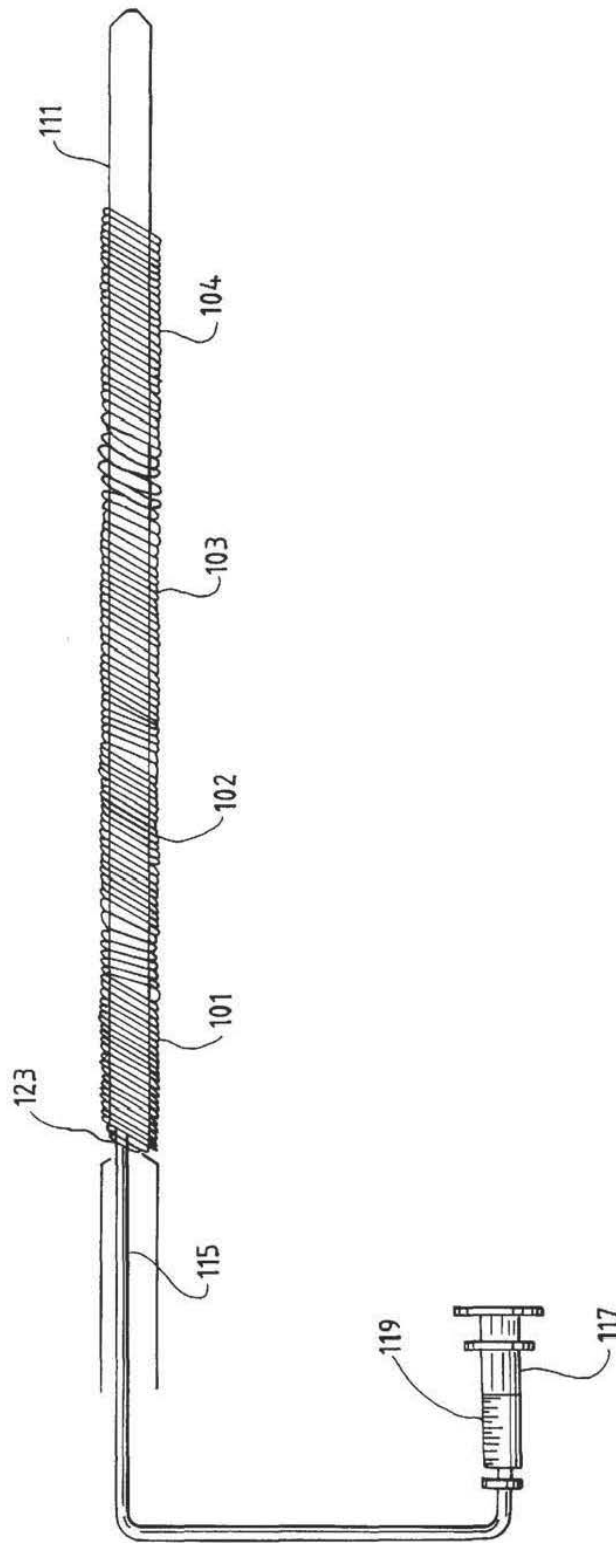
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FIG. 9a



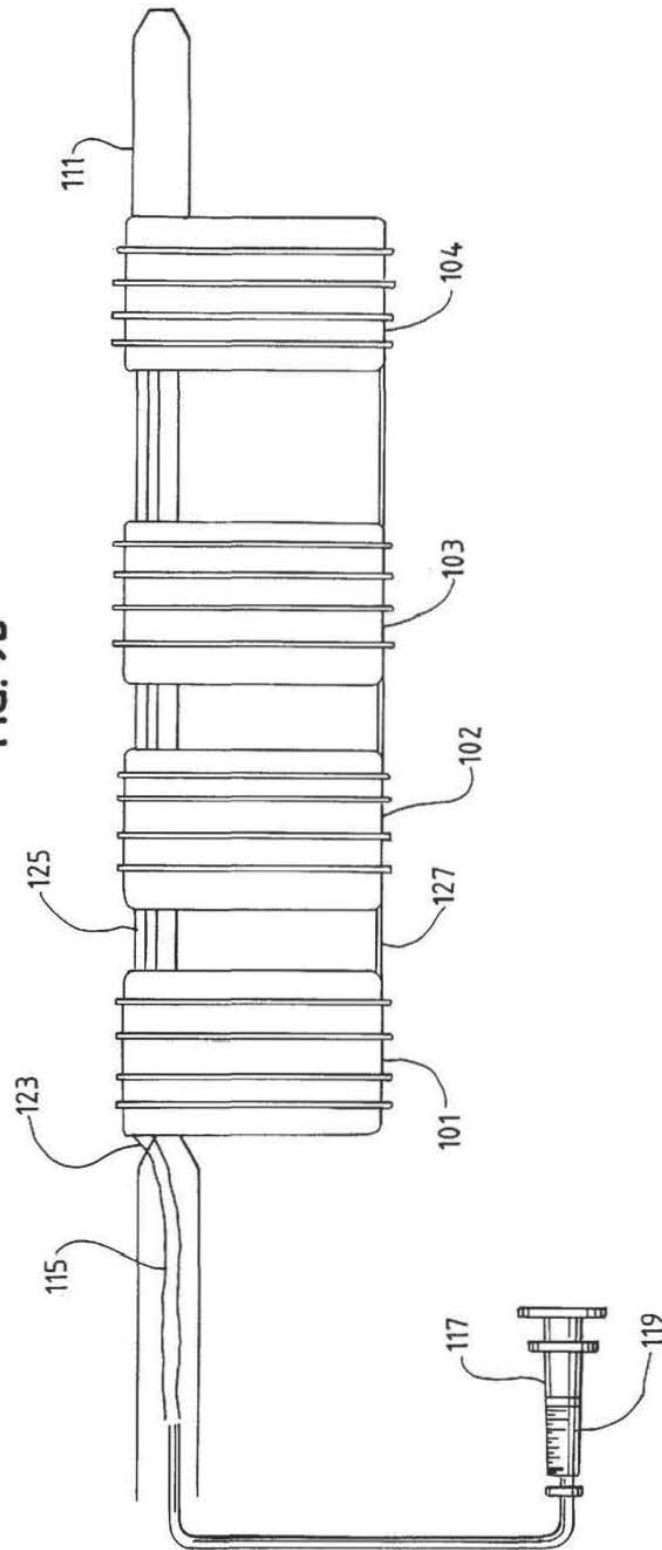
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FIG. 9b



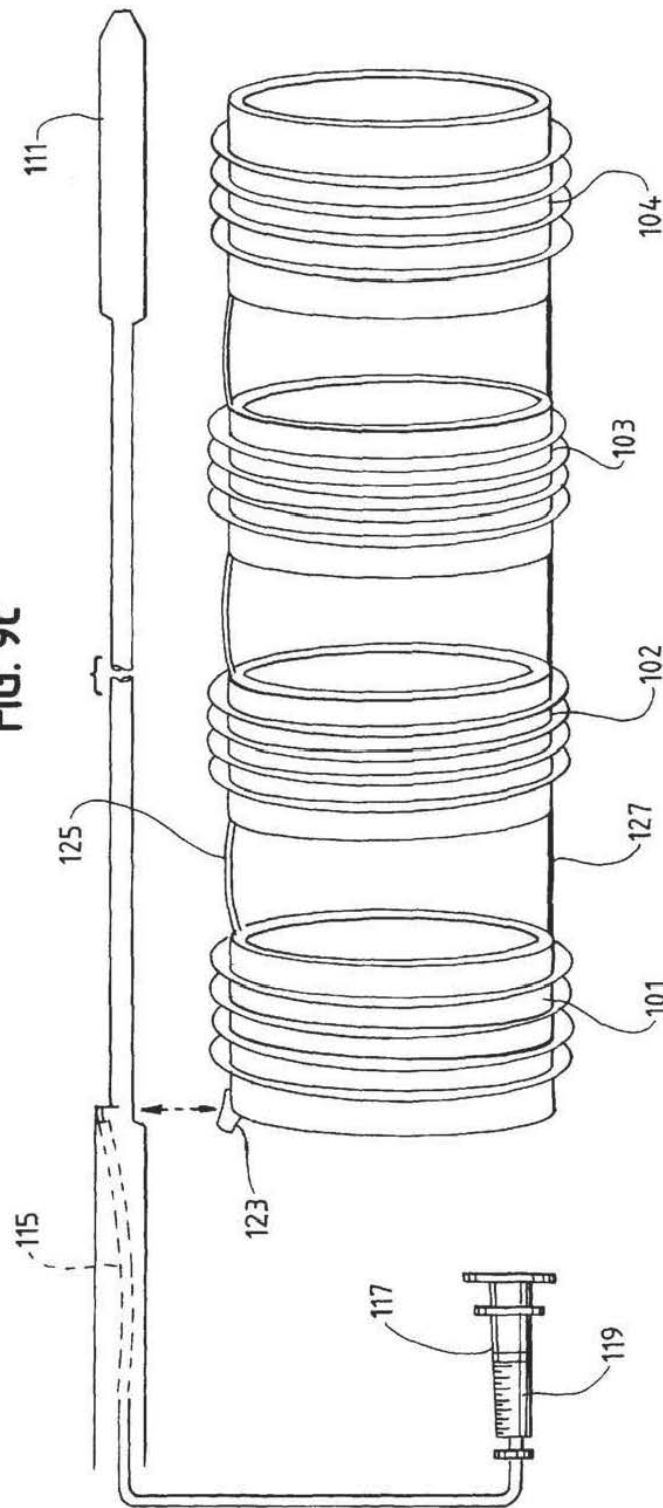
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FIG. 9c



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## INFLATABLE INTRALUMINAL STENT AND METHOD FOR AFFIXING SAME WITHIN THE HUMAN BODY

### BACKGROUND

Various tubular structures within the human body, such as the biliary duct system, excretory system and vascular system, may deteriorate so that medical repair is necessary. For example, weaknesses in the walls of the tubular structures or deteriorative diseases may affect the ability of the tubular structures to conduct fluids and, in turn, may be life threatening. Surgical and interventional radiological techniques have been a primary means of providing treatment for such problems. Such surgical and interventional radiological techniques involve inserting a catheter and other medical devices into the tubular structures through an incision in the patient's skin.

As an example, degenerative effects on blood vessels may cause a narrowing or constriction of the lumen of the vessel so that blood flow is restricted. Such a condition is known as "stenosis". Treatment of stenosis involves the use of a stent to permanently widen the portion of the vessel that is obstructed.

The use of stents in the treatment of stenosis is well known. Stents are tubular bodies having a diameter which may be increased once they are properly positioned within the tubular structure. There are a variety of different stent designs, but by far most are made of metal wire or ribbon. The most widely used method of deploying a stent involves the use of a dilation catheter having an inflatable balloon at its distal end. The stent, its diameter at a minimum, is positioned over the uninflated balloon portion of the dilation catheter. With the aid of fluoroscopy, the physician then positions the catheter and stent at the proper location within the tubular structure. The balloon is then expanded which in turn expands the stent in a radial fashion so that the stent, now having an enlarged diameter, supports the wall of the tubular structure. Next, the balloon is deflated and the catheter is removed. By virtue of its deformable metal construction, the stent remains positioned in tension against, and in support of the tubular structure wall upon removal of the balloon and catheter.

Problems exist with such an arrangement, however, in that the irregular surfaces of most metallic stents are likely to damage the endothelial walls of healthy arteries during delivery. Furthermore, once the stent is positioned, repositioning is difficult if not impossible. To further complicate matters, misplacement of the stent can lead to catastrophic results such as the complete occlusion of the tubular structure. Finally, the stent may ultimately lose its tension against the wall and migrate to an undesired location.

Some stent designs feature anchoring pins, surgical staple-like clips or exposed barbs to secure the stent to the tube walls via penetration of the walls. Damage to the tubular wall may occur when a such device is being positioned within the tube. Furthermore, repositioning of such stents cannot be accomplished without damaging the tube walls.

Due to the above problems, extensive fluoroscopic examination is required to ensure the correct placement of existing stent designs to minimize the risk of misplacement and tissue damage.

Accordingly, it is an objective of the present invention to provide a stent, and a method of placing it, that allows for repositioning of the stent within a tubular structure of the body. It is also an object of the present invention to provide

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a stent, and a method of placing it, that allows for the stent to be affixed to the tubular structure inner walls in a manner that prevents both damage to the walls and migration of the stent after it has been affixed.

A further problem with existing stent designs is that they do not allow for the stent to be used to secure other medical devices to the tube walls. Many interventional radiology procedures require the insertion of medical devices, other than a stent, into the lumen of the tubular structures of a patient.

As an example, aneurysms may occur in blood vessels having weakened walls. An aneurysm is a ballooning of the wall of an artery. Left untreated, the aneurysm will frequently rupture resulting in a loss of blood through the rupture. Aneurysm repair involves inserting a vascular prosthesis, also known as a graft or stent-graft, into the lumen of the damaged vessel to reconstruct the section that is in need of repair. Such grafts must be anchored within the lumen of the blood vessel at the location of the aneurysm. The utility of a stent would be greatly increased if it could be used for such a purpose.

As such, it is also an object of the present invention to provide a stent that may be utilized to secure other medical devices to the inner walls of the tubular structure.

### SUMMARY

The present invention is directed to an inflatable intraluminal stent and a method of among it to the interior surface of a tubular structure within the human body as a means of treating conditions such as stenosis. Intraluminal medical devices may also be attached to the inner surface of the stent. The stent of the present invention features an inflatable cuff having an inner surface, an outer surface, and an inlet and an outlet with a lumen extending therebetween. The outer surface has a friction-enhancing face that engages the interior surface of the tubular structure, without penetrating it, when the inflatable cuff is deployed.

If the initial placement of the stent within the tubular structure is not optimal, it may be deflated, repositioned to the optimal position and reinflated so as to again be affixed to the tubular walls via its outer surface. The tissue of the walls is not damaged or harmed by its exposure to the friction-enhancing face of the stent outer surface.

The stent is inflated with an inflation material that may contain a hardening agent. A valve, which is integral with the stent, allows it to be sealed in an inflated condition after it is placed in the proper position.

A number of the stents may be joined together so as to form a multi-ring stent. Such an arrangement may be used to affix medical devices which require more support due to their length or in situations requiring a stent of a length greater than the length of a single stent.

For a more complete understanding of the nature and scope of the invention, reference may now be had to the following detailed description of embodiments thereof taken in conjunction with the appended claims and accompanying drawings.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of an embodiment of the stent of the present invention;

FIG. 2 shows a vertical sectional view of the stent of FIG. 1 taken along line 1—1;

FIG. 3 shows a perspective view of another embodiment of the stent of the present invention;

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FIGS. 4a and 4b are enlarged partially broken away perspective views showing the detail of the mitre valve and breakaway valve connections of the stent of FIG. 1 in engaged and disengaged positions, respectively;

FIGS. 5a through 5d show in cross-section a constricted blood vessel with an elevational view of the stent of FIG. 1 being deployed therein in accordance with the method of the present invention;

FIGS. 6a through 6d show cross-sectional views corresponding to FIGS. 5a through 5b taken along line 2—2;

FIG. 7 shows a cross-sectional view of a blood vessel with an aneurysm and a stent-graft utilizing the stent of the present invention;

FIG. 8 shows a cross sectional view of an inferior vena cava with a filter disposed therein via the stent of the present invention;

FIGS. 9a through 9c show partial section, elevation and perspective views of another embodiment of the stent of the present invention, and the method of deploying the stent in accordance with the present invention, wherein multiple stents of the type of FIG. 1 are connected in a gang arrangement.

#### DESCRIPTION

Referring to FIG. 1, an embodiment of the inflatable intraluminal stent of the present invention is indicated generally at 5. The stent 5, shown in its inflated and deployed configuration, is a hollow cylinder and features an inlet 7, an outlet 9 and a lumen 15 extending between inlet 7 and outlet 9. The lumen of the stent is defined by an inflatable cuff; indicated generally at 17, having an inner surface 19 and an outer surface 23.

As shown in FIG. 1, outer surface 23 features a number of inflatable ridges 25 disposed about its circumference. While inflatable ridges are shown in the FIGS., any friction-enhancing outer surface, that would secure the inflated stent to the interior wall of a tubular structure without penetrating it, could be used. For example, the surface could feature nubs, bumps, indentations, etc.. As will be shown later, medical device may be secured to inner surface 19 of cuff 17 by way of biologically inert adhesives.

Inflatable cuff 17 is manufactured to the appropriate diameter and width to support or simulate the wall of, or to support a medical device within, the desired tubular structure of the patient. Inflatable cuff 17 is preferably constructed by extrusion and is drawn so as to have a low profile when viewed down the axis of the center of the ring defining cuff 17. Also, inflatable cuff 17 and its outer surface 23 are preferably composed of a polymeric plastic which is biologically inert. The material of cuff 17 must be able to withstand high inflation pressures and must be of sufficient durability to provide for decades of effective use within the body.

As illustrated in FIG. 2, circumferential ridges 25 are in fluid communication with the inflatable chamber 27 of cuff 17. Spot welds 28, positioned incrementally about the circumference and parallel with the longitudinal axis of cuff 17, prevent distention of the flat portions of the outer surface 23 of cuff 17.

As an example of an alternative friction-enhancing surface, another embodiment of the stent of the invention is shown in FIG. 3. As illustrated in FIG. 3, the outer surface 30 of the cuff is made coarse by a combination of raised portions 31 and lowered portions 33. These surface features allow the inflated stent to grip the interior walls of a tubular structure with a force that is sufficient to prevent its migration.

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In addition, it may be desirable in some applications to provide the cuff with an outer surface that promotes tissue ingrowth. This would allow the stent to become more integrated, and thus more firmly affixed, within the tubular structure as time progresses. Such a surface could be provided by combining a friction-enhancing surface, as discussed above, with a surface material such as TEFLON.

The cuff 17 is inflated and deflated by means of a valve, indicated generally at 37 in FIGS. 4a and 4b, which is integral with inflation port 39 of cuff 17. Preferably, valve 37 combines a breakaway valve 43 with a "duck bill" or "mitre" valve 45. Mitre valve 45 features opposing leaflets 51 and 53 which are constructed of a non-elastomeric, biologically inert material. Breakaway valve 43 features a circumferential rim 55 formed upon the interior surface of inflation port 39. Inflation tubing 61 features mating end 63 and circumferential notch 65. As shown in FIG. 4a, when inflation tubing 61 is in an engaged configuration with valve 37, mating end 63 separates opposing leaflets 51 and 53 so that cuff 17 may be inflated or deflated. When in this configuration, circumferential notch 65 engages circumferential rim 55 so as to secure inflation tubing 61 within inflation port 39.

Referring to FIG. 4b, once cuff 17 has been inflated (or deflated) to the desired level, a sharp tug on inflation tubing 61 in a direction away from inflation port 39 causes circumferential notch 65 and circumferential rim 55 to disengage. This allows easy withdrawal of mating end 63 from mitre valve 45 and inflation port 39. Upon withdrawal of the mating end 63 of inflation tubing 61, as shown in FIG. 3b, opposing leaflets 51 and 53 of mitre valve 45 close to seal the inflated cuff 17.

Referring back to FIG. 1, cuff 17 is inflated by way of an inflation syringe 71 with an inflation material 73. The inflation material could be a saline-based fluid or a material that contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens over time. Typically, the inflation syringe 71 is mounted in a screw-feed pressure generating device provided with a manometer in order to accurately gauge inflation pressures. After cuff 17 has been installed and inflated, the material 73 hardens over time to permanently affix stent 5 within the tubular structure of the body via circumferential ridges 25.

FIGS. 5a through 5d, and corresponding FIGS. 6a through 6d, illustrate the steps to be performed in deploying the stent of the present invention in accordance with the method of the present invention. Referring to FIGS. 5a and 6a, a guide wire 81 is initially fed from outside of the patient's body, through an incision and finally, through the constricted portion 83 of a blood vessel 85.

Once guide wire 81 is in place, catheter 87, with stent 89 collapsed over it, is advanced along guide wire 81 so as to become positioned at the constricted portion 83 of blood vessel 85, as shown in FIGS. 5b and 6b. Inflation tubing, not shown in this view, is located within catheter 87 and is connected to stent 89 by the valve arrangement described in connection with FIGS. 4a and 4b. Stent 89 is then inflated using the technique described above. As shown in FIGS. 5c and 6c, stent 89 is inflated so that the size of the lumen of stent 89 approximates the lumen size of the original, unconstricted blood vessel. By doing so, constricted portion 83 is compressed between blood vessel wall 85 and stent 89, the latter of which is fixed in place by way of protruding ridges 91.

A unique feature of the present invention is its capability of being optimally positioned within a tubular structure in

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the body (in this case, a blood vessel) without causing damage to the surrounding tissue. Specifically, after stent 89 has been inflated so that ridges 91 affix the stent to the tubular walls without penetration, the position of the stent is examined fluoroscopically to determine if it is optimal. If not, stent 89 may be deflated, repositioned and then re-inflated. It is important to note that the tissue of the vessel walls is not damaged by exposure to ridges 91 of the stent.

As the final step of the procedure, as shown in FIGS. 5d and 6d, catheter 87 is removed from stent 89 so that the former may be removed from the blood vessel. As discussed in reference to FIGS. 4a and 4b, breakaway and mitre valves allow the inflation tubing within catheter 87 to be removed from the stent so that the stent may be sealed in an inflated condition. Finally, guidewire 81 is removed from the blood vessel.

Note that utilization of the stent and method of the present invention for the treatment of stenosis is presented only as an example of its potential applications. A non-exhaustive list of other applications includes: placing filters in the inferior vena cava, use of the stent in the vascular or biliary system to maintain the patency of the respective tubular structures and endoarterial grafts via a percutaneous approach. In order to accommodate some of these applications, as stated earlier, an intraluminal medical device may be attached to the interior surface of the stent of the present invention.

As an illustration, FIG. 7 shows a stent-graft utilizing the stent of the present invention to treat an aneurysm. A graft 92 is held by its end portions to the interior surfaces of stents 94, shown in an inflated condition, by biologically inert adhesive 95. The stent-graft is secured to the vessel walls via ridges 96 so that blood passes through graft 92.

As another example, FIG. 8 shows a filter 97 disposed within the inferior vena cava via the stent of the present invention. Filter 97 is attached to the interior surface of stent 98. Stent 98, shown in an inflated condition, is held within the inferior vena cava by ridges 99. In some applications, it may be desirable to temporarily place filter 98 in the inferior vena cava. The stent of the present invention is perfectly suited to such an application in that it can be deflated for retrieval without damaging the interior walls of the inferior vena cava. In such instances, stent 98 is inflated with a saline-based material that does not contain a hardening agent. This allows for easy deflation of stent 98 for retrieval. During the retrieval process, stent 98 is deflated and the inflation stalk 100 is snared with a separate device. The stent and attached filter may then be removed from the inferior vena cava.

Referring to FIGS. 9a through 9c, a ganged arrangement of four inflatable stents, 101 through 104, is shown. Each of the stents is similar in construction to stent 5 of FIG. 1. Such an arrangement preferably is used to affix medical devices which require more support due to their length, such as long tubes or endo-arterial grafts. Alternatively, the ganged arrangement may be utilized in situations requiring a stent of a length greater than the length a single cuff. Examples include colonic or esophageal stents. FIGS. 9a through 9c also show how such a ganged arrangement may be deployed in accordance with the method of the present invention.

FIG. 9a shows the multi-ring stent collapsed over deployment catheter 111. FIG. 9a also illustrates that, via a partial sectional view of catheter 111, inflation tubing 115 is located within catheter 111 and connected at one end to stent 101 via port 123. Stent 101 features breakaway and mitre valves (not shown) of the type illustrated in FIGS. 4a and 4b within its

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port 123. As will be shown below, stents 101 through 104 are in fluid communication with one another. The opposing end of inflation tubing 115 is connected to inflation syringe 117 which is filled with inflation material 119.

FIG. 9b illustrates the multi-ring stent in an inflated condition, such as would be desired once the stent is properly positioned within the tubular structure of a patient. Connecting inflation tubing 125 interconnects stents 101 through 104 so that all four stents can be simultaneously inflated. The inflation tubing 125 and stents 101 through 104 are formed into an integral construction by fastening the stents to the inflation tubing, the latter of which is initially provided with apertures (not shown) for conveying fluid into the cuffs. Fastening may be performed using a biologically inert adhesive, thermal welding or any other suitable fastening method. In the configuration shown in FIG. 9b, inflation material 119 has been injected into stents 101 through 104 by manipulation of inflation syringe 117. Stents 101 through 104 are also secured together by stabilizing bridging wire 127 so as to enhance the integrity of the multi-ring stent. Note that tape may be used in place of wire 127.

FIG. 9c shows the inflated multi-ring stent after catheter 111 has been pulled away so that catheter 111 may be removed from the tubular structure of the patient. As the catheter is pulled away, the breakaway valve within port 123 releases inflation tubing 115 and the mitre valve seals port 123 in a manner similar to the one illustrated in FIG. 4b. As a result, inflation material 119 cannot escape from the multi-ring stent.

The present invention can be constructed in many different sizes and shapes. The only criterion which must be met is that the stent must be of an appropriate width and diameter so that the tubular wall may be simulated or supported by the stent or the medical device to be used can be fully supported within the tubular structure by the stent. Not only can the invention be practiced in small structures such as the vascular system, but also, the stent may be affixed within much larger structures such as the excretory system.

While the preferred embodiments of the invention have been shown and described, it will be apparent to those skilled in the art that changes and modifications may be made therein without departing from the spirit of the invention, the scope of which is defined by the appended claims.

What is claimed is:

1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:

- a) an inflatable and deflatable cuff of generally hollow cylindrical continuation having a collapsible lumen, an inner surface, an inlet, an outlet and a friction enhancing outer surface, said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff, said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;
- b) means for injecting an inflation material into said cuff to inflate it; and
- c) a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.

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2. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is a coarse surface.

3. The inflatable intraluminal stent of claim 1 further comprising a plurality of spot welds between the inner surface and the friction-enhancing outer surface of the inflatable cuff in staggered relationship with the inflatable protrusion(s) to limit distention between the inner surface and the friction-enhancing outer surface.

4. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.

5. The inflatable intraluminal stent of claim 4 wherein the material that promotes tissue ingrowth is TEFLON.

6. The inflatable intraluminal stent of claim 1 wherein the inflatable cuff is composed of a polymeric plastic which is biologically inert.

7. The inflatable intraluminal stent of claim 1 wherein the inflation material includes a hardening agent.

8. The inflatable intraluminal stent of claim 1 wherein the valve is a mitre valve.

9. The inflatable intraluminal stent of claim 1 wherein the valve is of a breakaway design to permit separation from the means for injecting.

10. The inflatable intraluminal stent of claim 1 further comprising means for securing an intraluminal medical device to the inner surface of the inflatable cuff.

11. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a graft for repairing aneurysms.

12. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a vena cava filter.

13. The inflatable intraluminal stent of claim 1 wherein the means for injecting an inflation material into said inflatable cuff to inflate it includes an inflation syringe and inflation tubing.

14. An apparatus for disposition within the lumen of a tubular structure within the human body comprising:

- a) a cuff having a collapsible lumen, an inner surface and a friction-enhancing outer surface with an inflatable and deflatable chamber disposed therebetween, the cuff also having an inflation port in fluid communication with the inflatable chamber,
- b) said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and affixing the cuff with the lumen of the tubular structure without penetration of the tubular structure when the cuff is fully inflated so that movement of the cuff in a longitudinal direction with respect to the tubular structure is prevented;

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c) means for inflating the cuff with inflation material in fluid communication with said inflation port; and

d) a valve integral with said inflation port for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.

15. The apparatus of claim 14 wherein the friction-enhancing outer surface is a coarse surface.

16. The inflatable intraluminal stent of claim 14 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.

17. The inflatable intraluminal stent of claim 10 wherein the material that promotes tissue ingrowth is TEFLON.

18. The apparatus of claim 14 wherein the valve is a mitre valve.

19. The apparatus of claim 14 wherein the valve is of a breakaway design to permit separation from the means for inflating.

20. The apparatus of claim 14 further comprising means for securing an intraluminal medical device to the inner surface of the cuff.

21. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a graft for repairing aneurysms.

22. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a vena cava filter.

23. An apparatus for disposition within the lumen of a tubular structure within the lumen body comprising:

- a) a plurality of cuffs, each of said plurality of cuffs having an inner surface and a friction enhancing outer surface with an inflatable chamber disposed therebetween, the inflatable chambers of said plurality of cuffs being in fluid communication with one another;
- b) said friction-enhancing outer surfaces featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and affixing the plurality of cuffs within the lumen of the tubular structure without penetration of the tubular structure when the plurality of cuffs are inflated;
- c) means for inflating the plurality of cuffs with inflation material; and
- d) a valve integral with one of the plurality of cuffs for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.

24. The apparatus of claim 22 further comprising means for securing an intraluminal medical device to the inner surfaces of the cuffs.

\* \* \* \* \*

**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT  
*Samuels v. TriVascular*, 2016-1490**

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